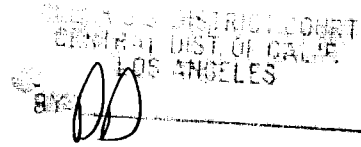


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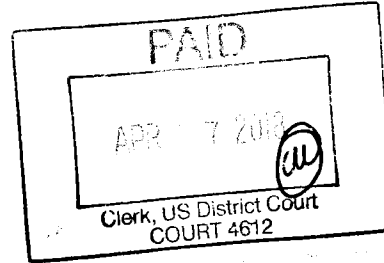
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IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA
and

THE STATES OF ARKANSAS,
CALIFORNIA, COLORADO,
CONNECTICUT, DELAWARE,
FLORIDA, GEORGIA, HAWAII,
ILLINOIS, INDIANA, IOWA,
LOUISIANA, MARYLAND,
MASSACHUSETTS, MICHIGAN,
MINNESOTA, MISSOURI,
MONTANA, NEVADA, NEW
JERSEY, NEW MEXICO, NEW
YORK, NORTH CAROLINA,
OKLAHOMA, RHODE ISLAND,
TENNESSEE, VERMONT, VIRGINIA,
WASHINGTON, AND THE DISTRICT
OF COLUMBIA

CV18-03591-DSF(JGx)
COMPLAINT FOR DAMAGES
AND DEMAND FOR JURY TRIAL

1 ex rel.

2 ALEXANDER VOLKOFF, LLC,

3 Relator,

4 vs.

5 JANSSEN PHARMACEUTICA N.V.,
6 JANSSEN PHARMACEUTICALS,
7 INC., and JANSSEN RESEARCH &
8 DEVELOPMENT, LLC, JOHNSON &
JOHNSON, and ORTHO-MCNEIL

9 Defendants.

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TABLE OF CONTENTS

INTRODUCTION	9
PARTIES.....	19
JURISDICTION AND VENUE	22
FACTS	23
A. Defendants Illegally Promoted Drugs for Dangerous Off-Label Uses.	23
i. Defendants’ off-label promotion of opioid drugs.....	27
ii. Defendants’ off-label marketing of Olysio	33
iii. Defendants’ off-label marketing of Xarelto	38
iv. Defendants’ off-label promotion of Levaquin.....	39
v. Defendants’ off-label promotion of Invokana	42
vi. Defendants’ off-label promotion of Simponi	43
vii. Defendants’ scheme to get off-label drug uses covered by insurance.	43
viii. Defendants sponsored seminars, symposia, and other continuing medical education programs that promoted the off-label use of their drugs.....	46
ix. Defendants provided financing and other support for questionable research to support and promote the use of their drugs in off-label patient populations..	47
B. Defendants Illegally Promoted Use of Their Drugs by Providing Kickbacks to Physicians and Researchers.	48
i. Defendants Paid Physicians Honoraria, and Lavish Meals to Attend or Speak at Events Promoting the Use of Opioid Drugs Nucynta, Nucynta ER, Ultram ER, and Duragesic, along with Olysio, Xarelto, Aciphex, Levaquin, Remicade, Elmiron, Aciphex, Invokana, Simponi, Elmiron, and Imbruvica, and other Defendants’ Drugs.	57
ii. Defendants Concealed Some Illegal and Fraudulent Payments to Physicians by Funneling Them through Third Party Consultant Companies.	63

1 iii. Defendants Knew Their Payments to Physicians Were Illegal Because They
2 Were Intended for the Purposeful Inducement of Business.63
3 iv. Defendants’ Payment of Illegal Kickbacks to Physicians Actually Affected
4 the Use of Opioid Drugs Nucynta, Nucynta ER, Ultram ER, and Duragesic,
5 along with Olysio, Xarelto, Aciphex, Levaquin, Remicade, Elmiron, Aciphex,
6 Invokana, Simponi, Elmiron, and Imbruvica, and other Defendants’ Drugs
7 among Doctors64
8 C. Defendants Illegally Promoted Use of Opioid Drugs Nucynta, Nucynta ER,
9 Ultram ER, and Duragesic, along with Olysio, Xarelto, Aciphex, Levaquin,
10 Remicade, Elmiron, Aciphex, Invokana, Simponi, Elmiron, and Imbruvica, and
11 other Drugs by Illegally Promoting a Spread between Published Pricing and the
12 Prices Offered to Customers.67
13 DEFENDANT’S ACTS OF RETALIATION76
14 DEFENDANTS’ SCHEMES RESULTED IN FALSE CLAIMS TO MEDICAID
15 AND MEDICARE86
16 CONCLUSION88
17 Count I; FALSE CLAIMS ACT88
18 CAUSING PRESENTATION OF FALSE OR FRAUDULENT CLAIMS88
19 Count II; FALSE CLAIMS ACT89
20 CAUSING A FALSE RECORD OR STATEMENT TO BE MADE OR USED
21 TO GET A FALSE OR FRAUDULENT CLAIM PAID OR APPROVED BY
22 THE GOVERNMENT89
23 Count III; FALSE CLAIMS ACT90
24 CAUSING FALSE RECORDS OR STATEMENT TO BE USED TO
25 CONCEAL AN OBLIGATION TO PAY MONEY TO THE GOVERNMENT
26 90
27 Count IV; FALSE CLAIMS ACT90

1	CAUSING PRESENTATION OF FALSE OR FRAUDULENT CLAIMS;	
2	ILLEGAL RENUMERATION	90
3	Count V; FALSE CLAIMS ACT	92
4	CAUSING A FALSE RECORD OR STATEMENT TO BE MADE OR USED	
5	TO GET A FALSE OR FRAUDULENT CLAIM PAID OR APPROVED BY	
6	THE GOVERNMENT; PROHIBITED REFERRALS, CLAIMS AND	
7	COMPENSATION ARRANGEMENTS	92
8	Count VI; FALSE CLAIMS ACT	93
9	CONSPIRING TO DEFRAUD THE GOVERNMENT BY GETTING A	
10	FALSE OR FRAUDULENT CLAIM ALLOWED OR PAID	93
11	Count VII	94
12	(Arkansas Medicaid Fraud False Claims Act, A.C.A. § 20-77-901 et seq.)	94
13	Count VIII	97
14	(California False Claims Act, Cal. Gov't Code § 12650 et seq.)	97
15	Count IX	99
16	(California Insurance Frauds Prevention Act, Cal. Ins. Code § 1871.7 et seq.)	99
17	Count X	101
18	(Colorado Medicaid False Claims Act, Col. Rev. Stat. §§ 25.5-4-303.5 et seq.)	
19	101
20	Count XI	104
21	(Connecticut False Claims Act for Medical Assistance Programs, Connecticut	
22	General Statutes § 17b-301b. et seq.)	104
23	Count XII	107
24	(Delaware Medicaid False Claims Act, 6 Del. C. § 1201 et seq.)	107
25	Count XIII	110
26	(District of Columbia Procurement Reform Amendment Act, D.C. § 2-308.13 et	
27	seq.)	110

1	Count XIV.....	112
2	(Florida False Claims Act, Fla. Stat. §§ 68.081 et seq.).....	112
3	Count XV	115
4	(Georgia State False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 et seq.)	
5	115
6	Count XVI.....	117
7	(Hawaii False Claims Act, Haw. Rev. Stat. § 661.21 et seq.).....	117
8	Count XVII	120
9	(Illinois Whistleblower Reward and Protection Act, 740 ILCS 175 et seq.) ...	120
10	Count XVIII	122
11	(Illinois Insurance Claims Fraud Prevention Act, 740 ILCS 92/1 et seq.).....	122
12	Count XIX.....	124
13	(Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5 et seq.)	
14	124
15	Count XX	127
16	(Iowa False Claims Act, Iowa Code § 685.1 et seq.)	127
17	Count XXI.....	130
18	(Louisiana Medical Assistance Programs Integrity Law, La Rev. Stat. Ann §	
19	437.1 et seq.).....	130
20	Count XXII	132
21	(Maryland Medicaid False Claims Against State Health Plans and State Health	
22	Programs Act, Annotated Code of Maryland § 2-601 et seq.)	132
23	Count XXIII	135
24	(Massachusetts False Claims Act, Mass. Gen. Laws Ann. Chap 12 § 5(A) et	
25	seq.)	135
26	Count XXIV	138
27	(Michigan Medicaid False Claim Act, M.C.L.A. 400.601 et seq.)	138

1	Count XXV	140
2	(Minnesota False Claims Act, (Minnesota Statutes § 15C.01 et seq.)	140
3	Count XXVI	143
4	(Missouri Health Care Payment Fraud and Abuse Act, Missouri Revised	
5	Statutes § 191.900 et seq.)	143
6	Count XXVII	146
7	(Montana False Claims Act, MT ST 17-8-401 et seq.)	146
8	Count XXVIII	149
9	(Nevada False Claims Act, N.R.S. § 357.010 et seq.)	149
10	Count XXIX	151
11	(New Jersey False Claims Act, N.J.S.A. 2A:32C-1 et seq.)	151
12	Count XXX	154
13	(New Mexico Medicaid False Claims Act, and New Mexico Fraud Against	
14	Taxpayers Act, N. M. S. A. 1978, § 27-14-1 et seq., and N. M. S. A. 1978, § 44-	
15	9-1 et seq.)	154
16	Count XXXI	157
17	(New York False Claims Act, N.Y. State Fin. Law § 187 et seq.)	157
18	Count XXXII	159
19	(North Carolina False Claims Act, North Carolina General Statutes § 51-1-605	
20	et seq.)	159
21	Count XXXIII	162
22	(Oklahoma Medicaid False Claims Act, 63 Okl. St. Ann. § 5053 et seq.)	162
23	Count XXXIV	164
24	(Rhode Island False Claims Act, Gen. Laws 1956, § 9-1.1-1 et seq.)	164
25	Count XXXV	167
26	(Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 et seq.)	
27	167

1 Count XXXVI169

2 (Vermont False Claims Act, 32 V.S.A. 630 et seq.).....169

3 Count XXXVII.....171

4 (Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1et seq.) 171

5 Count XXXVIII174

6 (Washington False Claims Act, Washington Revised Code § 74 66-005 et seq.)

7174

8 REQUESTS FOR RELIEF176

9 DEMAND FOR JURY TRIAL178

10 CERTIFICATION THAT VENUE IS PROPER179

11

12

13

14

15

16

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INTRODUCTION

Alexander Volkoff, LLC, (“Relator”) is informed and believes, and thereon alleges the following Complaint against Janssen Phamaceutica N.V., Janssen Phamaceuticals, Inc., and Janssen Research & Development, LLC, Johnson & Johnson, and Ortho-McNeil, (hereinafter collectively referred to as “Defendants”).

1. Defendant Janssen (“Janssen”) is a pharmaceutical company that produces, markets, sells, and distributes pharmaceutical and biological products in the areas of area of immunology, pain management, and infectious diseases among others.

Janssen and Defendant Johnson & Johnson (“JNJ”) and Defendant Ortho-McNeil (“Ortho-McNeil”) co-promote the prescription drug Olysio, or simeprevir, in the United States. Janssen also markets, sells, and distributes the opioid drugs Nucynta, Nucynta ER, Ultram ER, and Duragesic. Additionally, Janssen markets, sells, and distributes drugs for a variety of other uses, such as its other drugs Xarelto, Aciphex, Levaquin, Remicade, Elmiron, Aciphex, Invokana, Simponi, Elmiron, and Imbruvica.

2. The Food and Drug Administration (“FDA”) has approved Olysio for the treatment of patients with Hepatitis C. The FDA has approved Nucynta for the treatment of moderate to severe pain acute pain under three (3) months in duration. Other indications for other Defendants’ drugs include Levaquin for infections caused by designated, susceptible bacteria; Xarelto for a variety of specific blood thinning purposes; Aciphex for heartburn and reflux; Ultram ER and Duragesic for chronic pain; and Remicade for rheumatoid arthritis, psoriatic arthritis, ulcerative colitis, Crohn's disease, and ankylosing spondylitis. Remicade is also used to treat severe or disabling plaque psoriasis. Also, Elmiron for the relief of bladder pain or discomfort associated with interstitial cystitis; Invokana as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus;

1 Simponi for the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing
2 spondylitis, and ulcerative colitis; and Imbruvica for the treatment of mantle cell
3 lymphoma.

4 3. Olysio is an expensive drug, costing as much as \$25,000 per dose. In
5 addition, its market share is inherently limited, since it is approved for use only in
6 patients with Hepatitis C. According to the Centers for Disease Control, there are
7 approximately 17,000 patients newly diagnosed annually with hepatitis C. To
8 overcome these problems and gain a larger market for this drug, Defendants
9 created a plan to illegally market Olysio off-label to treat HIV and renal failure
10 patients, and other uses that are not approved by the FDA.

11 4. Defendants funneled millions of dollars in unrestricted grant money to
12 physicians in order to encourage them to speak and publish articles supporting the
13 use of Olysio in patients whose cardiovascular event symptoms did not meet FDA
14 criteria for Olysio. Specifically, Defendants targeted, developed, and trained
15 physician “Key Opinion Leaders” (“KOLs”), influential doctors whom Defendants
16 supported monetarily. Defendants, in turn, expected these KOLs to support
17 Defendants’ prescription drug use among off-label patient populations. Defendants
18 then pointed to the KOLs’ use of Olysio when promoting the drug widely to other
19 physicians throughout the country.

20 5. Consistent with their scheme to provide illegal incentives to doctors who
21 prescribed Olysio, Defendants also gave kickbacks to physicians for off-label use
22 of the drug, providing the physicians with speaking opportunities, unrestricted
23 educational grants, lavish meals, and honoraria to promote and prescribe Olysio
24 off-label, including paid travel included trips to Las Vegas, Hawaii, Chicago,
25 Dallas, and other locations. At these “fly-to” activities, doctors received paid travel
26 and speaker fees, and/or received speaker training so they could receive additional
27 speaker payments from Defendants in the future. Defendants encouraged the

1 physicians' acceptance of the paid travel and speaking fees as a form of quid pro
2 quo for increased sales of Olysio.

3 6. Additionally, Olysio is not superior to competing, similar prescription drugs
4 on the market, and Defendants' scheme to promote broad off-label use of Olysio
5 among off-label patient populations and to influence studies promoting Olysio for
6 use in such patients is very costly. A 2015 study published in the journal BMC
7 Gastroenterology reveals that Olysio is not a cost-effective treatment compared to
8 older treatments, and that a reduction of thirty percent (30%) or more in cost would
9 be necessary to achieve a cost-effective result (See Exhibit 1).

10 7. Many of Defendant's drugs have an inherently limited market share, because
11 they are approved for use only in patients with very narrow indications. To
12 overcome these problems and gain a larger market for these drugs, Defendants
13 created a plan to illegally sell and market its opioid drugs Nucynta, Nucynta ER,
14 Ultram ER, and Duragesic, and its other drugs Olysio, Xarelto, Aciphex, Levaquin,
15 Remicade, Elmiron, Aciphex, Invokana, Simponi, Elmiron, and Imbruvica, and
16 Defendants' other drug products to gain market share and formulary status in
17 different territories.

18 8. In order to increase sales of its opioid drugs Nucynta, Nucynta ER, Ultram
19 ER, and Duragesic, and its other drugs Olysio, Xarelto, Aciphex, Levaquin,
20 Remicade, Elmiron, Aciphex, Invokana, Simponi, Elmiron, and Imbruvica, and
21 Defendants' other drug products, Defendants have illegally provided monetary and
22 other incentives for physicians who were willing to prescribe the drugs.

23 Defendants trained, managed, and instructed its sales representatives, business and
24 marketing managers, and other executives to offer physicians cash payments,
25 expensive trips and meals, expensive gifts, and entertainment as kickbacks in
26 exchange for the physicians' agreement to prescribe Defendants' opioid drugs
27 Nucynta, Nucynta ER, Ultram ER, Duragesic, and its other drugs Olysio, Xarelto,

1 Aciphex, Levaquin, Remicade, Elmiron, Aciphex, Invokana, Simponi, Elmiron,
2 and Imbruvica, and Defendants' other drug products.

3 9. The pharmaceutical industry is highly regulated by the FDA. Pursuant to the
4 Food, Drug and Cosmetics Act, 21 U.S.C. §§ 301 *et seq.*, the FDA strictly
5 regulates the content of consumer and physician based advertising, direct to
6 physician product promotion, and drug labeling information used by
7 pharmaceutical companies in promoting and selling-FDA approved prescription
8 drugs.

9 10. Under 21 C.F.R. § 202.1(k)(2), any brochures, handouts, slide shows or
10 other such promotional materials aimed at physicians are deemed to be "product
11 labeling" and is regulated as such.

12 11. Under relevant FDA regulations, product labeling must be pre-approved by
13 the FDA and conform to very exacting requirements concerning, inter alia, drug
14 interactions, indicated uses and claims concerning competing products. See 21
15 C.F.R § 201.57.

16 12. All claims made in any labeling material must be truthful, not misleading
17 and represent a fair balance of the information presented. Any presentations,
18 promotions, or marketing to physicians for products for use other than that
19 approved for labeling purposes by the FDA is considered "off label" marketing and
20 is thus prohibited by FDA regulation.

21 13. Any failure to fairly and accurately represent the required information about
22 a prescription drug is considered misbranding and is a false and fraudulent
23 statement as a matter of law. See 21 U.S.C. §§ 331(a) and (b), 352(a), (f) and (n);
24 21 C.F.R. § 201.57.

25 14. Pharmaceutical promotional and marketing materials and presentations
26 lacking in fair balance or that are otherwise false or misleading violate the Food
27 Drug and Cosmetics Act, 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated

1 hereunder. Such violations exist where promotional and marketing materials and
2 presentations for an FDA approved drug:

3 a. Minimize, understate or misrepresent the risks, contra-indications and
4 complications associated with that drug;

5 b. Overstate or misrepresent the risks, contra-indications and
6 complications associated with any competing drugs;

7 c. Reference "off label" uses of the drug for which it was not an
8 approved indication by the FDA, or expressly or implicitly promote
9 unapproved uses and dosing regimens for which the drug is not indicated;

10 d. Make comparative claims about the drug that have not been
11 demonstrated by substantial evidence, such as comparisons with competing
12 drugs and/or drug indications of patient usage, warnings and safety claims
13 including side effects, physician preference, or

14 e. Are otherwise false, misleading or lacking in fair balance in the
15 presentation of information about the drug being marketed or any competing
16 drug.

17 15. When Defendants present physicians with false information about off-label
18 use of its opioid drugs Nucynta, Nucynta ER, Ultram ER, and Duragesic, and its
19 other drugs Olysio, Xarelto, Aciphex, Levaquin, Remicade, Elmiron, Aciphex,
20 Invokana, Simponi, Elmiron, and Imbruvica, and Defendants' other drug products,
21 and encourage physicians to prescribe and procure those drugs for off-label use
22 uses which are not approved by the FDA or substantiated by any relevant drug
23 compendium, Defendants cause physicians and facilities to submit bills for off-
24 label use of these Defendants' drugs that are based upon fraudulent and misleading
25 statements and are thus ineligible for reimbursement under federal Medicaid,
26 Medicare, and TRICARE programs, and under state health care systems.

1 16. Had the United States and the several States known that the Defendants
2 caused procurement of opioid drugs Nucynta, Nucynta ER, Ultram ER, and
3 Duragesic, along with Olysio, Xarelto, Aciphex, Levaquin, Remicade, Elmiron,
4 Aciphex, Invokana, Simponi, Elmiron, and Imbruvica, and Defendants' other drug
5 products for off-label uses and also caused those drugs to be prescribed for off-
6 label uses, they would not have provided reimbursement for such prescriptions.
7 This course of conduct violates the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*
8 and equivalent state statutes.

9 17. Federal laws and regulations governing Medicaid and Medicare and similar
10 state statutes prohibit pharmaceutical manufacturers from providing kickbacks to
11 physicians and medical care providers. Specifically, the federal healthcare anti-
12 kickback provision, 42 U.S.C. § 1320a-7b(b) (2)(B), provides:

13 [W]hoever knowingly and willfully offers or pays any remuneration
14 (including any kickback, bribe, or rebate) directly or indirectly, overtly or
15 covertly, in cash or in kind to any person to induce such person . . . to
16 purchase, lease, order, or arrange for or recommend purchasing, leasing, or
17 ordering any good, facility, service, or item for which payment may be made
18 in whole or in part under a Federal health care program, shall be guilty of a
19 felony and upon conviction thereof, shall be fined not more than \$25,000 or
20 imprisoned for not more than five years, or both.

21 18. The Medicare and Medicaid anti-kickback laws, 42 U.S.C. 1320a-7b(b), *et*
22 *seq.*, regulate drug and device marketing in order to prevent over-utilization of
23 medical care, medication, and medical drugs. Under the anti-kickback laws,
24 companies may not offer or pay any remuneration, in cash or kind, to induce
25 physicians or others to order or recommend drugs or devices which may be paid
26 for by a federal healthcare program such as Medicare or Medicaid. These
27 regulations not only prohibit outright bribes and rebate schemes, but prohibit any

1 payment, remuneration, gratuities, and other benefits paid by a company to a
2 physician which has as one of its purposes inducing the physician to use the
3 company's products.

4 19. In addition to the anti-kickback laws, §1877 of the Social Security Act,
5 often referred to as the "Stark law," provides that a physician cannot (1) refer
6 patients to an entity (2) for the furnishing of DHS (designated health services) (3)
7 if there is a direct or indirect financial relationship between the referring physician
8 (or an immediate family member of the referring physician) and the entity, (4)
9 unless the financial relationship fits within one of the specific exceptions in the
10 statute or regulations. *See* 42 U.S.C. §1395nn. Unlike the Medicare Anti-Kickback
11 Statute, which is a criminal statute requiring at least some measure of criminal
12 intent, the Stark Statute is a civil statute requiring strict compliance. Intent to
13 violate or substantial compliance has no bearing on whether an activity is or is not
14 legal. Violation, no matter how unintentional or technical, is sufficient to invoke
15 the Stark Statute. Lastly, if a prohibited referral occurs under Stark, the DHS entity
16 may not file or cause to be filed a claim under Medicare or Medicaid or a bill to
17 any individual, third party payer, or other entity for the designated health services
18 provided.

19 20. Had the United States and the several States known that Defendants' opioid
20 drugs Nucynta, Nucynta ER, Ultram ER, and Duragesic, and its other drugs
21 Olysio, Xarelto, Aciphex, Levaquin, Remicade, Elmiron, Aciphex, Invokana,
22 Simponi, Elmiron, and Imbruvica, and Defendants' other drug products were being
23 used by facilities because physicians in those facilities had accepted kickbacks
24 from Defendants, the United States and the several States would not have funded
25 these illegal kickbacks after the fact by providing reimbursement for Defendants'
26 drugs.

27 21. Defendants' conduct occurred while under concurrent Corporate Integrity
28

1 Agreements (2010 and 2013) for two (2) separate FDA off-label promotion
2 schemes. The extent of these infractions only indicates that the defendant has no
3 respect for the law and is willing to push legal boundaries in pursuit of corporate
4 profits despite what this may entail for the US government or patients' lives.

5 22. Moreover, the kickbacks described in this Complaint are strictly illegal and
6 have had the direct effect of greatly increasing the amount of Defendants' opioid
7 drugs Nucynta, Nucynta ER, Ultram ER, and Duragesic, and its other drugs
8 Olysio, Xarelto, Aciphex, Levaquin, Remicade, Elmiron, Aciphex, Invokana,
9 Simponi, Elmiron, and Imbruvica, and other Defendants' drugs that have been paid
10 for and reimbursed by state and federal governments. Accordingly, the kickbacks
11 have had the indirect effect of increasing the amount of money spent by the federal
12 government and the States for payments and reimbursements covered by Medicaid,
13 Medicare, and the TRICARE health care system for members of the military and
14 their families. Defendants' kickbacks to physicians represent the inducement of
15 payment from the government through a pattern of fraudulent conduct, constituting
16 false claims within the meaning of 31 U.S.C. § 3729 and the relevant provisions of
17 the state false claims and Medicaid fraud statutes. When Relator ALEXANDER
18 VOLKOFF, LLC complained and reported these practices and other illegal and
19 fraudulent practices to Defendants, Janssen retaliated against Relator and then
20 eventually fired Relator.

21 23. Relator also alleges violations by Defendants of the California Insurance
22 Frauds Prevention Act ("CIFPA"), Cal. Ins. Code § 1871, *et seq.*; and the Illinois
23 Insurance Claims Fraud Prevention Act ("ILCFPA"), 740 Ill. Comp. Stat. § 92/1,
24 *et seq.*

25 24. Both California and Illinois have *qui tam* statutes that permit relators to raise
26 allegations of fraud by individuals or entities against private insurance companies.

1 The statutes operate similarly to the federal and state FCAs, and are written to
2 prevent fraud occurring in the private health care insurance market.

3 25. Upon information and belief, Defendants receive significant revenues from
4 private insurers in California and Illinois.

5 26. Upon information and belief, Defendants are paid by private insurers that
6 cover California- and Illinois-based patients who have been referred for treatment
7 as a result of Defendants' scheme.

8 27. Upon information and belief, private healthcare insurance companies in
9 California and Illinois require the same conditions of payment and prohibitions
10 kickbacks and off-label marketing found in the Medicare and Medicaid programs.

11 28. The CIFPA prohibits as unlawful the following:

12 ...It is unlawful to knowingly employ runners, cappers, steerers, or other
13 persons...to procure clients or patients to perform or obtain services or
14 benefits under a contract of insurance or that will be the basis for a claim
15 against an insured individual or his or her insurer.

16 29. The Defendants' kickback scheme also violates Section 1871.7(a) of the
17 CIFPA, Cal. Ins. Code 1871.7(a), and Section 92/5(a) of the ILCFPA 740 Ill.
18 Comp. Stat. § 92/5(a). Defendants have entered into illegal arrangements with
19 physicians that provide financial incentives for the use of their drug prescribing
20 services, resulting in inappropriate claims submitted to private insurers.

21 30. Under the CIFPA, any interested person may bring a sealed civil action for a
22 violation of Section 187.7 on behalf of the State of California, Ca, Ins. Code §
23 1871.7(e)(1), (2). If the relator is ultimately successful and the District Attorney
24 intervenes in the lawsuit, the relator is entitled to the recovery of fees, expenses,
25 and a relator's share of between 30% and 40% according to the priority specified in
26 the statute. Cal. Ins. Code § 1871.7(g)(1)(A)(iii)(I), (IV). If neither the District
27 Attorney nor the Insurance Commissioner intervene and the relator is successful in

1 settling his/her lawsuit or attaining final judgment, the relator may receive between
2 40% and 50% of the proceeds plus costs and expenses. Cal. Ins. Code §
3 1871.7(g)(2)(A).

4 31. The Illinois Insurance Claims Fraud Prevention Act ("ILCFPA") is similar
5 to the CIFPA. In Section 92/5(a), the ILCFPA prohibits kickbacks and states:

6 ... [I]t is unlawful to knowingly offer or pay any remuneration directly or
7 indirectly, in case or in kind, to induce any person to procure clients or
8 patients to obtain services or benefits under a contract of insurance or that
9 will be the basis for a claim against an insured person or the person's insurer.

10 32. 740 Ill. Comp. Stat. § 92/5(a). If a defendant is in violation of Section
11 92/5(a) or specifically identified corollary criminal code sections, he/she must
12 reimburse three times the amount of money defrauded as well as civil penalties
13 ranging from \$5,000.00 to \$10,000.00 per fraudulent claim. 740 Ill. Comp. Stat. §
14 92/5(b).

15 33. Pursuant to Section 15 of the ILCFPA Section 15, an interested person may
16 bring a sealed civil action for a violation of the ILCFPA on behalf of him/herself
17 and the State of Illinois. 740 Ill. Comp. Stat. § 92/15(a), (b). If the State's Attorney
18 and/or the Attorney General intervene in the *qui tam* action, and it is ultimately
19 successful, the relator is entitled to at least 30% of the recovery. 740 Ill. Comp.
20 State § 92/25(a). If neither government entity intervenes and the relator
21 successfully pursues the lawsuit on his/her own, the relator is entitled to recover
22 not less than 40% of the proceeds. 740 Ill. Comp. Stat. § 92/25(b).

23 34. Relators here are the original sources of the allegations under the CIFPA and
24 ILCFPA.

PARTIES

35. Relator has worked in pharmaceutical sales since 2005, when Relator began working as a sales representative in Los Angeles, California for Janssen, promoting the multiple prescription drugs, including those contained in this complaint.

36. Relator is a citizen of the United States. Relator has been employed by Defendants and has inside knowledge that is independent of and materially adds to publicly disclosed information regarding Defendants' business related to pharmaceutical products.

37. The Relator became aware of Defendants' false claim scheme alleged herein due to Relator's position as an original source. The Relator commenced this *qui tam* action against Defendants for the pharmaceutical products at issue based upon Relator's personal experiences and industry insider information. Relator, as an employee of Defendants, had access to pricing, marketing and reimbursement information such as proprietary Defendant computer files revealing the marketing schemes, prices, and volume of sales by Defendants. Relator, as an industry insider, discovered huge profit spreads on the drugs at issue and that the drugs at issue were reimbursed by Medicare, Medicaid, and private insurers for illegal marketing schemes. Relator directly witnessed and observed the Defendants' sale and introduction of the drugs into the stream of commerce. Relator was aware that Medicare and Medicaid intended to reimburse Defendants for drugs based on a belief that the drugs were legitimately marketed and that the drugs were not encumbered by illegal kickback and off-label marketing schemes, when in fact the Defendants heavily influenced sales of the drugs with kickbacks and off-label promotion.

38. The facts averred in this Complaint are based entirely upon the personal observations of Relator and documents in Relator's possession.

1 39. Relator has provided or is providing to the United States Attorney and the
2 Attorneys General of Arkansas, California, Colorado, Connecticut, Delaware,
3 Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland,
4 Massachusetts, Michigan, Minnesota, Missouri, Montana, Nevada, New Jersey,
5 New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee,
6 Vermont, Virginia, Washington, and the District of Columbia a full disclosure of
7 substantially all material facts supporting this Complaint, as required by the False
8 Claims Act, 31 U.S.C. § 3730(b)(2), and relevant state statutes.

9 40. Relator filed the case of *U.S. et al. ex rel. Alexander Volkoff LLC*, Case No.
10 2:16-cv-06997-RGK-RAO in the Central District of California on September 16,
11 2016, which was dismissed by the District Court on April 19, 2018, after an
12 Amended Complaint that named “Alexander Volkoff, LLC” as the relator had been
13 filed. The “Alexander Volkoff, LLC” of that case is the sole member of Alexander
14 Volkoff LLC, and is the insider who worked for Defendants’ companies and
15 experienced first-hand all of the facts regarding Defendants’ fraudulent schemes as
16 described in both of these cases. This action arises from an identical set of facts as
17 the previously-filed action.

18 41. Janssen N.V. is a corporation organized and existing under the laws of
19 Belgium with its principal place of business at Turnhoutseweg 30, B-2340, Beerse,
20 Belgium.

21 42. Janssen Pharm. is a corporation organized and existing under the laws of
22 Pennsylvania with its principal place of business at 1125 Trenton-Harbourton
23 Road, Titusville, New Jersey 08560.

24 43. Janssen R&D is a corporation organized and existing under the laws of New
25 Jersey with its principal place of business at 920 Route 202, Raritan, New Jersey
26 08869.

1 44. Janssen is a biopharmaceutical company engaged in the manufacture,
2 promotion and sale of pharmaceutical products in interstate commerce regulated by
3 the FDA, which activities are subject to the Food, Drug, and Cosmetic Act
4 (“FDCA”), the Food and Drug Administration Modernization Act (“FDAMA”) and regulations promulgated pursuant thereto. Janssen markets, sells, and
5 distributes the prescription drug Olysio, which is indicated in the treatment of
6 certain patients with hepatitis C, and the prescription drug Nucynta, which is
7 indicated in the treatment of chronic pain, Nucynta ER, Xarelto, Ultram ER,
8 Duragesic, Aciphex, Levaquin, Remicade, Elmiron, Aciphex, Invokana, Simponi,
9 Elmiron, Imbruvica, among other drugs.

10 45. JNJ is a fictitious name adopted by Defendant JOHNSON & JOHNSON
11 COMPANY, a New Jersey corporation which has its principal place of business at
12 One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey
13 08933.

14 46. Defendant JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN
15 PHARMACEUTICA INC. f/k/a ORTHO-MCNEIL-JANSSEN
16 PHARMACEUTICALS, INC. (“JANSSEN PHARM”) is a Pennsylvania
17 Corporation, having a principal place of business at 1125 Trenton-Harbourton
18 Road, Titusville, New Jersey 08560.

19 47. Defendant JANSSEN ORTHO LLC (“JANSSEN ORTHO”) is a limited
20 liability company organized under the laws of Delaware, having a principal place
21 of business at Stateroad 933 Km 01, Street Statero, Gurabo, Puerto Rico 00778.
22 Defendant JANSSEN ORTHO is a subsidiary of Johnson & Johnson. The only
23 member of JANSSEN ORTHO LLC is OMJ PR Holdings, which is incorporated
24 in Ireland with a principal place of business in Puerto Rico. Accordingly,
25 JANSSEN ORTHO LLC is a citizen of Delaware, Ireland, and Puerto Rico for
26 purposes of determining diversity under 28 U.S.C. § 1332.

1 48. Since 2005, Defendants have been co-conspirators and co-partners in the
2 production, promotion, marketing, sales, and distribution of its opioid drugs
3 Nucynta, Nucynta ER, Ultram ER, and Duragesic, and its other drugs Olysio,
4 Xarelto, Aciphex, Levaquin, Remicade, Elmiron, Aciphex, Invokana, Simponi,
5 Elmiron, and Imbruvicaa, and Defendants' other drug products and are thus jointly
6 and severally liable for the acts described herein related to the production,
7 promotion, marketing, sales, and distribution of these drugs.

8 **JURISDICTION AND VENUE**

9 49. This action arises under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*
10 This Court has jurisdiction over this case pursuant to 31 U.S.C. §§ 3732(a) and
11 3730(b). This court also has jurisdiction pursuant to 28 U.S.C. § 1345 and 28
12 U.S.C. § 1331. This court has jurisdiction over the state law counts asserted in this
13 Complaint under both 31 U.S.C. § 3732(b) and 28 U.S.C. § 1367, because the state
14 claims arise from the same transaction or occurrence as the federal claims and
15 because these claims are so related to the federal claims that they form part of the
16 same case or controversy under Article III of the U.S. Constitution.

17 50. At all times material to this Complaint, Defendants regularly conducted
18 substantial business within the State of California, maintained permanent
19 employees and offices in California, and made and are making significant sales
20 within California. Defendants are thus subject to personal jurisdiction in
21 California.

22 51. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a) because
23 Defendants transact business in this district, selling and promoting their drugs to
24 multiple doctors in this district.

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FACTS

A. Defendants Illegally Promoted Drugs for Dangerous Off-Label Uses.

52. Defendants created a plan to illegally market Olysio off-label to treat HIV and renal failure patients, and other uses that are not approved by the FDA.

Defendants additionally created schemes to illegally market the opioid pain drugs Nucynta, Nucynta ER, Ultram ER, and Duragesic, in ways that increased the risk of addiction. Defendants also illegally marketed Xarelto, Levaquin, Invokana, Simponi, and other drugs in dangerous off-label manners.

53. New pharmaceutical drugs may not be marketed in the United States until the sponsor of the drug has proven to the Food and Drug Administration (FDA) that the drug is safe and effective for specific indications at specified dosages (if applicable). The indications and dosages (if applicable) approved by the FDA are set forth in the product's labeling, the content of which is also approved by the FDA. Although it is not unlawful for physicians to use drugs for indications or at dosages different than those set forth in a product's labeling, the Food Drug and Cosmetic Act prohibits pharmaceutical companies from marketing or promoting approved drugs for uses other than those set forth in the drug's approved labeling. This regulatory structure protects patients and consumers by ensuring that medical companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific governmental body.

54. The Medicaid and Medicare programs also rely on the FDA's findings regarding safe and effective uses for approved drugs. The Omnibus Budget Reconciliation Act of 1990 limited Medicare reimbursement for drugs or devices to "covered outpatient drugs" 42 U.S.C. § 1396r-8(k)(2)(A). Covered outpatient drugs only include drugs used for "medically accepted indications". A medically accepted indication is a use which has been approved by the FDA or one which is

1 supported by specific compendia set forth in the Medicare statutes. Until August,
2 1997, none of the compendia referenced in the statutes supported off-label usage of
3 any approved drugs or devices. Even after August 1997, off-label usage was
4 significantly restricted.

5 55. Off-label use of a medical product refers to the prescription or use of a
6 product in a manner not approved by the FDA. Since Congress passed the Food
7 and Drug Administration Modernization Act ("FDAMA") in November 1997,
8 manufacturers may provide off-label studies to the medical community only if
9 certain conditions are met. Moreover, federal law prohibits manufacturers from
10 promoting off-label uses through physician studies when the investigating
11 physician is not truly independent or impartial, as well as when the physician is in
12 fact an agent of the manufacturer based upon significant financial relationships.
13 See 21 U.S.C. §§ 360aaa *et seq.*

14 56. Whether a drug is FDA-approved for a particular use will largely determine
15 whether payment for that drug will be reimbursed under the federal and state
16 Medicaid and Medicare programs. Thus, the off-label use of such drugs is not
17 eligible for reimbursement under Medicaid. Likewise, many state health care
18 agencies intend not to reimburse for drugs for off-label purposes because the
19 agencies do not want to spend money on drugs not recognized as medically
20 necessary in sources specified by federal law. Defendants' opioid drugs Nucynta,
21 Nucynta ER, Ultram ER, and Duragesic, and its other drugs Olysio, Xarelto,
22 Aciphex, Levaquin, Remicade, Elmiron, Aciphex, Invokana, Simponi, Elmiron,
23 and Imbruvica were not eligible for reimbursement from federal or state Medicaid
24 or Medicare programs when prescribed for use in off-label patients.

25 57. Defendants' conduct caused physicians to submit bills for their drugs that
26 were ineligible for reimbursement under Medicaid and Medicare because the drugs
27 were used for off-label purposes. Defendants' actions caused physicians, hospitals,

1 and clinics to prescribe, purchase and use Olysio. Such prescriptions, purchases
2 and use were not eligible for reimbursement under Medicaid and Medicare because
3 the drugs were for an off-label use. According to Relator, up to ninety-eight (98%)
4 of Olysio use in 2014 was for off-label purposes. Defendants thus caused the
5 submission of false claims for payment of money under the federal Medicaid and
6 Medicare programs and state health care programs.

7 58. Additionally, the United States military's payments to cover the use of
8 Defendants' opioid drugs Nucynta, Nucynta ER, Ultram ER, and Duragesic, and
9 its other drugs Olysio, Xarelto, Aciphex, Levaquin, Remicade, Elmiron, Aciphex,
10 Invokana, Simponi, Elmiron, and Imbruvica, and Defendants' other drug products
11 for off-label patient populations were not eligible for coverage under the
12 TRICARE health care plan for members of the military and their families
13 (formerly known as CHAMPUS), or through direct purchasing by the military. The
14 Department of Defense will generally pay for the costs only of "proven" drugs,
15 meaning drugs that have been found to be "safe and effective" by the FDA. 32
16 C.F.R. § 199.4(g)(15)(i)(A). TRICARE will pay for off-label use of a drug only if
17 the use is determined to be a "medical necessity" and if the program can determine
18 that the off-label use is "safe and effective and in accordance with nationally
19 accepted standards of practice in the medical community." *Id.* TRICARE will not
20 pay for a drug unless "reliable evidence shows that the medical treatment or
21 procedure has been the subject of well-controlled studies of clinically meaningful
22 endpoints". 32 C.F.R. § 199.4(g)(15)(i)(C). The studies Defendants supported to
23 promote the use of Olysio off-label did not meet these standards. Had TRICARE
24 known this, it would not have covered or reimbursed the off-label use of
25 Defendants' opioid drugs Nucynta, Nucynta ER, Ultram ER, and Duragesic, and
26 its other drugs Olysio, Xarelto, Aciphex, Levaquin, Remicade, Elmiron, Aciphex,
27 Invokana, Simponi, Elmiron, and Imbruvica, and Defendants' other drug products.

1 59. In limited situations, investigational drugs may be used by the military.
2 However, whenever a member of the armed forces receives a drug unapproved for
3 its applied use, the member must be given notice and consent to such use. 10
4 U.S.C. § 1107. In order to waive consent for the purposes of using such an
5 “investigational drug” in battle, the Secretary of Defense must request a waiver
6 from the President. No such waiver was requested for Defendants’ opioid drugs
7 Nucynta, Nucynta ER, Ultram ER, and Duragesic, and its other drugs Olysio,
8 Xarelto, Aciphex, Levaquin, Remicade, Elmiron, Aciphex, Invokana, Simponi,
9 Elmiron, and Imbruvica, and Defendants’ other drug products.

10 60. As described in this Complaint, Defendants have, since at least 2005
11 through the present, knowingly and intentionally violated the regulatory schemes
12 described above in its marketing of Defendants’ products. Defendants knew or
13 should have known that thousands of pharmacies would routinely and necessarily
14 file false claims with the federal government when the pharmacies sought federal
15 reimbursement for its opioid drugs Nucynta, Nucynta ER, Ultram ER, and
16 Duragesic, and its other drugs Olysio, Xarelto, Aciphex, Levaquin, Remicade,
17 Elmiron, Aciphex, Invokana, Simponi, Elmiron, and Imbruvica, and Defendants’
18 other drug products. But for Defendants’ actions most, if not all, of the false claims
19 for the purchase of Defendants’ products would never have been submitted.
20 Although in some cases the pharmacists did not directly contract with the federal
21 government, Defendants were the indirect beneficiary of all of the false claims
22 submissions described in this Complaint.

23 61. While all on-label and off-label sales made or effected by the health care
24 providers receiving unlawful kickbacks or engaging in improper self-referral cause
25 false claims to be filed, the unlawful promotion of off-label uses of Defendants’
26 products provides an additional, independent, and, under the circumstances, far
27 more urgent basis for the government to interdict this activity—the public health is

1 at risk.

2 *i. Defendants' off-label promotion of opioid drugs*

3 62. Opioid drugs have the potential for patient addiction, abuse, and misuse,
4 resulting in life-threatening overdoses. Defendants downplayed this risk, and
5 marketed the opioid drugs Nucynta, Nucynta ER, Ultram ER, and Duragesic, as
6 natural and less addictive than other drugs. Although evidence was building up that
7 long-acting extended release ("ER") opioids should only be used as a last resort for
8 pain management, Defendants ignored the signs and continued to push these highly
9 addictive drugs using misleading terms.

10 63. Nucynta (tapentadol) is a Schedule II opioid agonist tablet and oral solution
11 first approved in 2008 and indicated for the "relief of moderate to severe acute pain
12 in patients 18 years of age or older." Nucynta is indicated for the treatment of acute
13 pain under three (3) months of duration. The company used multiple approaches to
14 increase market capture of the product. To both market it as a stand-alone short
15 acting medication, in addition to another long acting agent, and in conjunction with
16 Opioid rotation. Until January 2015, Janssen developed, marketed, and sold
17 Nucynta and Nucynta ER, the "extended release" formula.

18 64. Nucynta ER (tapentadol extended release) is a Schedule II opioid agonist
19 tablet first approved in 2011 and indicated for the "management of pain severe
20 enough to require daily, around-the-clock, long-term opioid treatment and for
21 which alternative treatment options are inadequate." Prior to April 2014, Nucynta
22 ER was indicated for the "management of moderate to severe chronic pain in
23 adults [and] neuropathic pain associated with diabetic peripheral neuropathy
24 (DPN) in adults." The DPN indication was added in August 2012.

25 65. Ultram ER (tramadol hydrochloride extended release) is a Schedule IV
26 opioid agonist tablet. It was first approved in the U.S. in 1995. Like Nucynta ER,
27 Ultram ER is indicated for "the management of pain severe enough to require daily

1 around-the-clock, long-term opioid treatment and for which alternative treatment
2 options are inadequate.”

3 66. Defendants promoted the dangerous and contraindicated idea that pain
4 should be treated first by taking long-acting opioids like Nucynta ER, Ultram ER,
5 and Duragesic continuously and then by taking short-acting, rapid onset opioids on
6 top of that. Extended release formulas are only indicated where shorter-acting
7 formulas are inadequate. Meanwhile, despite the short acting nature of the drug,
8 the marketing efforts for Nucynta were concentrated on high volume pain
9 prescribers such as pain management specialists and rheumatologist that primarily
10 treat chronic pain patients. Short-acting Nucynta (November 20, 2008) went on the
11 market about three (3) years before the long-acting form, Nucynta ER (August 25,
12 2011). The drug was marketed based on its so-called ascending and descending
13 pathways, part of a claim that the drug was non-addictive, and avoided withdrawal
14 symptoms.

15 67. While it was once thought that long-acting opioids would not be as
16 susceptible to abuse and addiction as short-acting ones, this view has been
17 discredited by innumerable adverse reaction reports. Since they claimed there was
18 an ascending and descending pathway component to the opioid, the Defendants
19 claimed the risk would be small. The FDA has enacted special risk evaluation
20 mitigation requirements for extended release and long-acting opioids. The FDA
21 has stated that these extended-release opioid drugs represent a significant overdose,
22 addiction, and death problem for large numbers of patients.

23 68. The emphasis on descending and ascending pathway served to ensure that
24 the risk for addiction was minimal even with long term use, and thus ignoring the
25 potential for addiction, tolerance, and the schedule II nature of the product.

26 69. Janssen trained, managed and instructed its sales representatives to expand
27 the label by advising physicians to stack Nucynta in addition to other long acting
28

1 opioids for additional pain relief. Physicians were encouraged to prescribe Nucynta
2 as a part of an “opioid rotation regimen” whereby it is indicated that risk of
3 tolerance would be decreased if the patient rotates through medications. This
4 information is unsubstantiated in literature and there is no indication that adding
5 additional Nucynta on a long acting opioid would be safe and effective for the
6 patient.

7 70. In 2013, in response to a petition to restrict the labels of long-acting opioid
8 products, the FDA noted the significant risks of opioids, including overdose, death
9 and addiction. The FDA recognized that opioids can cause death, coma, and life-
10 threatening respiratory depression even when properly used under the supervision
11 of a physician. The FDA required that—going forward—opioid makers of long-
12 acting formulations clearly communicate these risks in their labels. The FDA also
13 required the warnings to be placed on promotional and marketing materials for the
14 drugs distributed by manufacturers.

15 71. Thus, the FDA confirmed that the adverse outcomes from opioid use include
16 death, unintentional overdose, and addiction, and that long-acting or extended
17 release opioids should only be used in cases where other treatments are not capable
18 of achieving the needed effect.

19 72. Notably, in reaching its conclusion, the FDA did not rely on new or
20 otherwise previously unavailable scientific studies regarding the properties or
21 effects of opioids. The information had been available all along, and Defendants
22 actively concealed it.

23 73. For example, a 2008 Janssen marketing piece for detailing pharmacists
24 emphasized neuroplasticity, that theoretically someone using Nucynta could
25 change pain chemistry and prevent “neuronal remodeling” to prohibit the
26 progression into chronic pain (See Exhibit 2). Essentially, this is a claim that
27 Nucynta would help patients actually get better, not just treat their pain. Chronic
28

1 pain develops when a patient is in pain so long that their brain undergoes “neuronal
2 remodeling” which basically means that the brain resets to be in a pain state
3 constantly. Thus, claiming that Nucynta would prevent this neuronal remodeling
4 implies that Nucynta would somehow address the underlying cause of the pain,
5 which is totally unsubstantiated.

6 74. In fact, Janssen denied that Nucynta ER was an opioid, and said it had
7 “weak” μ -opioid activity, and the majority of the pain relief was the result of
8 adjuvant activity from serotonin and norepinephrine re-uptake, rather than any
9 opioid effect.

10 75. For example, one 2009 Nucynta promo piece profiles a 40-year-old African
11 American male police officer who was hurt on the job. It recommends Nucynta for
12 lower risk pain relief, due to its treatment of pain “by addressing both ascending
13 and descending pathways” and its combination of “opioid and nonopioid activity in
14 one centrally acting oral analgesic (See Exhibit 3).

15 76. Janssen sales representatives were instructed to tell prescribers that Nucynta
16 ER, Ultram ER, and Duragesic, “reach steady state, and essentially there’s no
17 dumping of the medication in the central nervous system.” This was to indicate
18 that they did not produce a rush or euphoric effect, and therefore were less
19 addictive and less likely to be abused. Janssen trained and directed its sales
20 representatives to use a similar statement for immediate release Nucynta – a
21 marketing line that it had a “dual mode of action”, and that it was safer due to the
22 “neuroplasticity of the brain.”

23 77. Janssen sales representatives were instructed to emphasize to physicians that
24 the majority of Nucynta’s pain relief came from serotonin and norepinephrine, and
25 that it has a weak affinity to μ -opioid receptors. They were told to claim that it
26 was about “1/50th” of the effect of morphine on the μ -opioid receptors,” and that
27 “it tickles the μ -opioid receptors.” This is not true, however, as Nucynta’s label
28

1 notes that the drug contains tapentadol, an opioid agonist and Schedule II
2 substance with abuse liability similar to other opioid agonists, legal or illicit.

3 78. Nucynta has weak activity on the μ -opioid receptor and achieves the
4 majority of its adjuvant pain relief properties from norepinephrine and serotonin
5 inhibition. This fact was repeated to tout the low potential for addiction to the
6 medication. This is a claim that is not supported by the label and again is used to
7 encourage broad adoption of the medication in patient populations where its use is
8 not warranted and is not deemed safe and effective by the label.

9 79. Janssen's sales representatives told prescribers that Nucynta's unique
10 properties virtually eliminated the risk of addiction associated with the drug.

11 80. This marketing exploitation is further supported by the compensation
12 structure of the sales representatives. The representatives were paid by baseline
13 growth of Nucynta prescriptions, not by the number of new prescriptions
14 indicating that the physicians are expected to have their patients on medication
15 above and beyond the on label ninety (90) day period. Since both compensation,
16 and retention of employment were based on the representatives' sales numbers,
17 this put additional pressure on representative to exploit these niches as their
18 employment and livelihood depended on it.

19 81. In discussions with prescribers, Janssen sales representatives omitted
20 discussion of addiction risks related to many other of Janssen's drugs. Janssen's
21 sales representatives left REMS packages ["REMS" or Risk Management Protocol
22 that is released for opiates] for the physicians without additional explanation of
23 what that necessarily meant for the patient and the physician. In fact, in a Quality
24 Assurance training session the company asserted that this is the package that is
25 necessary for new compounds with no indication that there is an additional risk for
26 addiction may be the actual reason for the REMS program. [Risk Management
27 Protocol that is released for opiates].

1 82. Beginning in or about 2008, Janssen trained, managed and instructed its
2 sales representatives to market to prescribers that Nucynta's unique properties
3 virtually eliminated the risk of addiction associated with the drug. Janssen told
4 physicians that Nucynta's unique properties virtually eliminated the risk of
5 addiction associated with the drug. In discussions with prescribers, Janssen sales
6 representatives omitted discussion of addiction risks related to Janssen's drugs.

7 83. Janssen sales representatives told prescribers that Nucynta and Nucynta ER
8 were "weak opioids" in a class of their own, implying that the risks of addiction
9 and other adverse outcomes associated with opioids were not applicable to
10 Janssen's drugs. In truth, however, as set out in Nucynta's FDA-mandated label,
11 Nucynta "contains Tapentadol, an opioid agonist and Schedule II substance with
12 abuse liability similar to other opioid agonists, legal or illicit."

13 84. For example, a February, 2009 Janssen coaching sheet for training its sales
14 representatives indicates that the low incidence of nausea and vomiting and the low
15 the incidence of constipation, CNS, dizziness, somnolence and pruritus are
16 important sales messages. Additionally, sales representatives were coached to push
17 the "low discontinuation rates due to" adverse events, and a "low incidence of
18 opiate withdrawal symptoms." (See Exhibit 4).

19 85. For example, a document called the "Nucynta Launch Vis Aid – An
20 Annotated Guide" from 2009 was also used to coach sales representatives on their
21 Nucynta messages. This document also promoted the "low composite incidence of
22 nausea and vomiting," low discontinuation rates, and "low incidence of withdrawal
23 symptoms." These statements did not accurately reflect the studies they referenced,
24 which did not address patients on the drug for more than ninety (90) days or with
25 chronic pain – a large target for the Nucynta sales team (See Exhibit 5).

26 86. For example, another 2009 sales training booklet, called "Opioid Efficacy
27 Meets Unexpected Tolerability" made the same claims of low rates of
28

1 discontinuation, adverse events, and withdrawal symptoms in the same flawed
2 manner based on the same studies (See Exhibit 6).

3 87. Janssen sales representatives told prescribers that patients on Defendants'
4 drugs were less susceptible to withdrawal than those on other opioids. Janssen
5 sales representatives told prescribers that Nucynta was not an opioid, making it a
6 good choice for chronic pain patients who previously were unable to continue
7 opioid therapy due to excessive side effects. This statement was misleading
8 because Nucynta is an opioid and has the same effects as other opioids.

9 88. Nucynta IR and ER were combined for payment of sales commissions –
10 Janssen expected patients to be on Nucynta IR long-term, and they were
11 compensating sales representatives based on long-term Nucynta IR prescriptions
12 (Exhibit 7).

13 89. For example, in or around 2012, on a field ride with the Nucynta Product
14 Director, Haya Teitel, Dr. Avrom Gart asserted that he had a patient that had
15 experienced temporary blindness while on Nucynta. The Marketing Director
16 requested that the representative not report the incident as it would “jeopardize the
17 launch” of the medication. Regardless the representative reported the incident
18 under “visual disturbance.” This is parallel to company’s overall culture to further
19 expand the indication of the medications while simultaneously reducing the
20 perceived rate of occurrence of side effects to encourage physician’s comfort in
21 prescribing medications broadly despite the off-label use and the clinical
22 appropriateness for the patients.

23 *ii. Defendants’ off-label marketing of Olysio*

24 90. Olysio’s FDA New Drug Application (“NDA”) number is NDA 205123.
25 The FDA’s approved use of Olysio is limited to the treatment of patients with
26 hepatitis C, in combination with Peginterferon alfa and Ribavirin (not alone), not
27 in patients with moderate or severe hepatic impairment or who have previously

1 failed on Olysio or other HCV protease inhibitors.

2 91. In 2014, Olysio was widely prescribed off-label, nearly twenty percent
3 (20%) of the treated genotype 1 patients were receiving a regimen containing
4 Janssen's Olysio, with the majority of these patients being prescribed the off-label
5 combination of Olysio plus Sovaldi with or without Ribavirin. Trending analysis
6 from the previous sampling period shows that off-label prescribing of this
7 combination had more than doubled, with thirty percent (30%) of specialists in one
8 study reporting having patients currently prescribed the regimen (See Exhibit 8).

9 92. According to marketing data presented at corporate training meetings
10 between the months of November 2013 – November 2014, ninety-eight percent
11 (98%) of Olysio prescriptions were written in an off label manner, for dual therapy
12 based on the COSMOS trial which included only thirteen (13) patients per each
13 arm of the treatment Q80K polymorphism. Those that were suffering from HIV
14 infection would need to take a drug holiday from their current HIV treatment in
15 order to be treated. This was dual therapy instead of the proven and less expensive
16 triple therapy regimen, and also included kidney compromised patients. At least
17 one of these patients has reportedly died as a result of this experimentation (See
18 Exhibit 9).

19 93. Janssen devised a marketing plan to promote off-label uses of Olysio
20 through promotion of the COSMOS study, and Janssen management disseminated
21 the instructions directly to sales representatives at national sales meetings and
22 through weekly or monthly local sales meetings. Sales representatives were pushed
23 to promote Olysio use as part of an off-label dual-therapy regimen in accord with
24 the COSMOS study, when only a triple-regimen therapy was approved by the
25 FDA. The COSMOS study was therefore distributed and left behind with the
26 physician customers to push the dual-therapy regimen model. Sales representatives
27 were instructed to tell physician customers, “your colleagues are using dual-

1 therapy as described in the COSMOS study” and left the study with the physician.
2 Sales representatives were instructed to tell physicians that patient sustained viral
3 response (“SVR”) would be better under a COSMOS model of dual-therapy, and
4 would result in fewer hospitalizations and complications.

5 94. However, the FDA’s approved use of Olysio was limited to the treatment of
6 patients with hepatitis C, in combination with Peginterferon alfa and Ribavirin (not
7 alone), not in patients with moderate or severe hepatic impairment or who have
8 previously failed on Olysio or other HCV protease inhibitors.

9 95. Meanwhile, the company enjoyed a \$2.3 billion windfall as a result of this
10 strategic off label promotion. Defendant JNJ CEO Alex Gorsky addressed the
11 investors that this surplus is a windfall and knowing that the drug simply didn’t
12 have the efficacy or the opportunity to compete in the market (See Exhibit 10).

13 96. The Olysio niches that were to be exploited versus the competition by
14 Janssen sales representatives included combination use with cholesterol lowering
15 medication such as Lipitor (atorvastatin); and renally compromised patients as
16 presented by sales marketing materials that consisted of speaker slide decks that
17 the company prepared for their paid physician speakers, and district business plans
18 from 2013 to 2015 (See Exhibits 11, 12, and 13).

19 97. Speakers were encouraged to talk about their success with pre and post liver
20 transplant patients, again a population in which the medication has not been proven
21 to be safe or effective. The FDA indicated that this usage with patients on
22 concomitant cholesterol lowering medication is not deemed safe or effective and in
23 fact seven (7) patients were reported injured as a result. Despite this, Defendants’
24 sales representatives were pushed to actively promote this use (See Exhibit 14).

25 98. Speakers were expected to set up a friend in the audience at Olysio dinners
26 to ask about off-label use, giving the speaker the opportunity to answer in a way
27 that promoted the off-label, dual-therapy regimen with Olysio that was in accord
28

1 with the COSMOS study. If no one in the audience remembered to ask about off-
2 label use, then the Janssen sales representative was expected to ask a question
3 about off-label use to give the speaker the opportunity to promote Olysio off-label.

4 99. These experimental regimens not only endangered the patient, they also
5 caused an unhealthy cost burden to the healthcare system.

6 100. For example, Defendants had Dr. Tram Tran moderate a Newport Liver
7 society meeting (See Exhibit 15). Dr. Tran was overheard by Relator asserting that
8 the cost of re-treating Hepatitis-C patient failures on this experimental system is
9 nearly \$1 million dollars.

10 101. It is important to note that the Olysio sales team was using the
11 term "spontaneous" as a euphemism for "off-label sales." Sales representatives
12 were following the "spontaneous users" (off-label prescribing physicians) very
13 closely, as were sales managers and National Sales Director Bill Whyte.

14 102. For example, in a document regarding a "field ride" with Janssen sales
15 manager Mo Issa, a sales representative noted that he was taking Issa to visit three
16 (3) of the top Olysio prescribers in his territory, all of whom were using Olysio in
17 the "spontaneous" manner. This showed the focus of Ron Lloyd and his manager
18 on increasing the business with these "spontaneous" off-label prescribers (See
19 Exhibit 16).

20 103. For example, in a September 16, 2014 document, Janssen National Sales
21 Director Bill Whyte instructed a sales representative to take him to see Dr. Tong
22 and Dr. Mena at their liver transplant center. Dr. Tong and Dr. Mena were using
23 Olysio off-label for their liver transplant patients, and the document made note of
24 their high prescribing volume of Olysio and Sovaldi, and their status within the
25 company as "KOL & National Speakers." The document noted that Dr. Tong and
26 Dr. Mena are "using spontaneous use of Olysio" (See Exhibit 17).

27 104. Dr. Myron Tong is a liver center doctor at Pasadena Liver Center who works
28

1 with Dr. Edward Mena. In 2015, Relator was reprimanded by her Janssen sales
2 manager Tyana Grant for not helping Dr. Tong to pull through an insurance
3 payment approval on a genotype-2 patient (Olysio was only indicated for hepatitis
4 C, Genotype 1). Relator refused to participate due to her concerns about the safety
5 of this off-label use. Dr. Tong wanted this treatment for one specific patient. Dr.
6 Tong asked Relator to work with CVS pharmacy, and to pass information to the
7 pharmacy and to help with the pull through on the insurance prior authorization
8 requirement on that patient. Relator refused to do the off-label pull-through, and so
9 was reprimanded by her manager Tyana Grant, on orders from her regional
10 manager Mo Issa. Mo Issa claimed that Relator was not working hard enough and
11 needed to do this pull-through. Relator defended Relator's self by saying that what
12 Dr. Tong was intending to do was off-label and potentially dangerous, and Relator
13 did not feel comfortable assisting him. Manager Tyana Grant told Relator that she
14 was hearing several similar complaints from other doctors where Relator was
15 unwilling to do the prior authorization work they required on their off-label
16 prescriptions.

17 105. From 2014-2015, Dr. Myron Tong wanted Relator to invite every possible
18 doctor to his speaker programs, but no more than ten (10) doctors would show up.
19 Dr. Tong specifically requested the Asian community physician attendees, but they
20 were outside Relator's territory. Dr. Tong wanted these doctors to attend his
21 speaker programs because they were potential referral partners for him. Dr. Tong
22 would sometimes shout at the Relator that Relator was not getting enough people
23 to his speaker programs.

24 106. Defendants continue to promote Olysio for use in off-label patient
25 populations, even in the face of evidence that such use led to an increased risk of
26 adverse events and even death. In fact, upon information and belief, Janssen
27 continues to promote Olysio for off-label use in off-label patient populations in the

1 same manner as set forth in this Complaint today.

2 107. Given these risks, it is difficult to see how the benefits of using Olysio for
3 patients with HIV and renal failure or other off-label indications for Defendants'
4 drugs outweigh the risks.

5 *iii. Defendants' off-label marketing of Xarelto*

6 108. Xarelto (rivaroxaban) is advertised as a wonder drug — a “next generation”
7 blood thinner to replace warfarin for prevention of blood clots and stroke.
8 Unfortunately, Xarelto’s makers chose not to warn that the drug also causes
9 uncontrollable internal bleeding that may lead to death. That calculated decision
10 has led to hundreds of deaths and many more injuries.

11 109. Janssen minimized the need for an antidote indicating that Coumadin is an
12 old paradigm that needed to be changed. True to its core business strategy, Janssen
13 has positioned Xarelto as the #1 NOA [Novel Oral Anti-coagulant] in the market,
14 expanding the label and minimizing the potential side effects of this dangerous
15 drug. Since the launch of Xarelto, hundreds of patients have died as a result of
16 irreversible internal bleeds.

17 110. The U.S. Food and Drug Administration (FDA) has approved Xarelto for a
18 number of specified uses, including: For hip and knee replacement patients, to
19 avoid and treat deep vein thrombosis (DVT) and pulmonary embolism (PE); and
20 for nonvalvular atrial fibrillation (NVAf) patients, to minimize the risk for stroke.

21 111. However, Defendants promoted Xarelto off-label in that it was not indicated
22 for medically ill patients. Defendant had employees calling on hospitals and
23 hematologists, whereas cardiologists and general practitioners and internists would
24 have been the appropriate, on-label targets. Defendants minimized the bleeding
25 deaths in the trials, and told doctors that there was no problem with reversal of the
26 bleeding problem, “because we aren't seeing a bleeding problem.”

27 112. There were twenty-two (22) deaths at the end of one Xarelto trial that

1 Defendants claimed were due to inaccuracy of the trial design. Additionally,
2 Janssen chose to aggressively market to patients on dialysis and medically ill
3 patients despite the fact that the FDA did not grant this label exception. Janssen
4 extensively targets oncologists and nephrologists although the safety and efficacy
5 has not borne out Xarelto's use in these patients.

6 113. Before Xarelto and other blood thinners like it came on the market, doctors
7 prescribed Warfarin (Coumadin) or heparin. The problem with Warfarin is that
8 users must take the drug at mealtime, eat a limited diet and have their blood
9 monitored frequently. These restrictions are unnecessary with Xarelto, as Janssen
10 claims. But Xarelto can cause bleeding, and once bleeding starts, Xarelto does not
11 have a simple method of stopping it. In this way, Xarelto is more dangerous than
12 Warfarin, where internal bleeding can be quickly stopped with vitamin K or
13 plasma.

14 114. Janssen also directed that Xarelto be actively promoted to oncologists,
15 nephrologists and hematologists, although there is no indication for medically ill
16 patients (See Exhibit 18).

17 *iv. Defendants' off-label promotion of Levaquin*

18 115. Levaquin (levofloxacin) is an antibiotic in the fluoroquinolone class,
19 indicated in adults (≥ 18 years of age) with infections caused by designated,
20 susceptible bacteria. It is indicated for: Pneumonia: nosocomial and community
21 acquired; Acute bacterial sinusitis; Acute bacterial exacerbation of chronic
22 bronchitis; Skin and skin structure infections, both complicated and
23 uncomplicated; Chronic bacterial prostatitis; Urinary tract infections, both
24 complicated and uncomplicated; and for Acute pyelonephritis Inhalational anthrax,
25 post-exposure. It is also indicated for plague.

26 116. However, the FDA issued a drug safety alert that the agency is requiring the
27 manufacturer of the antibiotic Levaquin (levofloxacin), Ortho-McNeil-Janssen
28

1 Pharmaceuticals, and of other fluoroquinolone drugs revise the labeling to warn
2 patients of the risk of serious side effects including nerve damage. Previously,
3 these drugs were implicated in tendon tears and ruptures in the arms and legs, also
4 serious injuries and heart damage including aortic dissection.

5 117. Defendants misrepresented the risk of tendon tears to physicians, telling
6 them only 1 in 10,000 patients had tendon ruptures (Achilles tendon tears were the
7 more common). Sales representatives were told and directed to make it sound as
8 safe as drinking coffee.

9 118. Defendants required representatives to sell Levaquin for all anti-biotic
10 purposes, as a much stronger anti-biotic than Cipro. At the Defendant's urging,
11 physicians were using to it off-label for all sorts of antibiotic purposes, and quite
12 commonly for upper respiratory infections.

13 119. Levaquin is used for mild upper respiratory infections such as acute
14 bronchitis, which is usually a self-limiting disease. Defendants touted Levaquin as
15 the work-horse quinolone antibiotic; safe and effective for use in both upper
16 respiratory and genitourinary infections. While many doctors and thousands of
17 patients have complained about the many adverse events associated with this
18 strong medication, Janssen decided to push the envelope with this medication and
19 encouraged doctors to use it as their go-to broad spectrum antibiotics from minor
20 urinary tract infections to upper respiratory infections despite the danger of
21 developing antibiotic resistance strains of bacteria, and despite the many reported
22 side effects reported by the patients that the company has treated dismissively.

23 120. Levaquin targets DNA gyrase and Topoisomerase 4 and as a very strong
24 antibiotic, Janssen used this platform to falsely indicate that the development of
25 resistance to this antibiotic is extremely low. This has not borne out in any clinical
26 study, local antibiograms nor has it been substantiated by the CDC as a means to
27 lower the incidence of MRSA. The indiscriminate use of this strong antibiotic in

1 fact may have contributed to the rise of MRSA in the local and national
2 community.

3 121. Additional, undisclosed adverse effects of Levaquin included patients who
4 were "floxed" – since Levaquin is a chemotherapy agent, it deactivates two points
5 in cell replication, targeting the DNA. Physicians were told that it targets the
6 bacterial DNA not the human DNA, and that widespread off-label use would
7 therefore be safe.

8 122. Patients who have been "floxed" have routinely reported suffering adverse
9 effects such as widespread bodily pain, fatigue, muscle weakness, muscle
10 twitching, muscle wasting, gait disturbances, severe balance issues, stiffness,
11 spasms, joint pain, tendon issues, seizures, tremors, numbness, burning, tingling,
12 fasciculation, spasticity, nerve damage, autonomic issues, voice issues, exercise
13 intolerance, difficulty swallowing, slow digestive motility, abdominal pain, acid
14 reflux, gastritis, nausea, constipation, diarrhea, colitis, cognitive impairment,
15 memory impairment, cardiac issues, urinary issues, kidney damage, liver damage,
16 pancreatic damage, thyroid abnormalities, hair loss, glucose issues, respiratory
17 issues, emotional issues, depression, psychosis, depersonalization, dissociation,
18 anxiety, insomnia, abnormal dreams, suicidal thoughts, thought alterations,
19 agitation, fatigue, dizziness, inability to concentrate, panic attacks, difficulty
20 communicating, forgetfulness, bruising, vision issues, hearing issues, tinnitus,
21 dental issues, gum issues, skin issues, rashes, multiple chemical sensitivity, sexual
22 dysfunction, reproductive issues, and DNA damage.

23 123. Defendants warned the FDA that the drug's adverse reactions also included
24 abnormal heart rhythms known as arrhythmias in addition to existing concerns
25 about heart problems and the potentially deadly Stevens Johnson Syndrome that
26 has dogged Zithromax for some time. However, the Defendants have not
27

1 adequately addressed the adverse events of the “floxed” patients in the drug’s
2 labeling, or adequately begun warning doctors against its continued off-label use.

3 124. In fact, the Defendants minimized the potential for tendon rupture and did
4 not disclose the thousands of permanent or otherwise persistent neurological side
5 effects that have been reported by many patients since launch. The company
6 marketing team asserted that the risk for developing a tendon injury is less than
7 one in 10,000 patients, that this is a class effect, and that in fact the large majority
8 the cases are because of competing antibiotic drug Cipro. Thereby Defendants
9 minimized the true side effects of this powerful agent that also has acted as a
10 chemotherapy agent and a DNA disruptor.

11 125. Relator is aware of one physician named Dr. James Jung who reported to
12 Relator and a sales manager that he personally suffered paralysis as a side effect of
13 Levaquin, and another physician named Dr. Spira who reported that he personally
14 suffered a ruptured tendon as a side effect of Levaquin. In each case, Defendants’
15 sales managers told Relator that the side effects would not be reported to the FDA,
16 as the managers felt they were unrelated to the drug.

17 *v. Defendants’ off-label promotion of Invokana*

18 126. Invokana (canagliflozin) is indicated for treatment of type 2 diabetes.
19 Defendants downplayed the risk of foot and leg infections. Diabetes patients are
20 already at risk of developing foot and leg infects. In 2016, the FDA updates the
21 Boxed Warning to warn that Invokana doubled the risk of foot and leg infections.
22 127. Defendants also downplayed the side-effect risk of yeast infections with
23 Invokana, which was a significant risk because diabetes patients are already more
24 susceptible to yeast infection.

25 128. Defendants also promoted Invokana off-label as a weight loss drug, without
26 scientific support.

27 ///

1 *vi. Defendants' off-label promotion of Simponi*

2 129. Defendant drug Simponi was indicated for a number of conditions, including
3 ulcerative colitis. Janssen promoted it off-label to treat all other inflammatory
4 bowel diseases (which are autoimmune diseases), rather than just ulcerative colitis.
5 Other inflammatory bowel diseases Simponi was promoted for off-label include:
6 Crohn's, Behcet's, diversion colitis, microscopic colitis.

7 *vii. Defendants' scheme to get off-label drug uses covered by*
8 *insurance.*

9 130. Defendants trained sales representatives on off-label and kickback-based
10 sales in "best practices meetings" which occurred at every national sales meeting.
11 Sales representatives were put through intensive training called "grinders," "round
12 robin," and "role playing" at these sales meetings, and Defendants paid doctor
13 customers to do the role playing during the sales training. Physicians were offered
14 free travel and one day of pay to participate in the role playing.

15 131. Defendants' sales representatives and Medical Science Liaisons ("MSL")
16 were trained to use knowingly off-label information to persuade physicians to use
17 Defendants' drugs. Defendants trained and directed sales staff to tell doctors that
18 Defendants' drugs are effective for a variety of off-label claims; none of which
19 were indications which the FDA had approved for Defendants' drugs. These
20 efforts were successful to promote the drug off-label. Collaboration with MSLs
21 was utilized as a means to expand and extend the label and make the physicians
22 comfortable with extensive off label use (98% in 2014 in combination with
23 Sovaldi).

24 132. Collaboration also occurred between Janssen sales representatives and
25 pharmacists at various specialty pharmacies in order to pull-through off-label
26 prescriptions. "Pull-through" is the process by which a drug company sales
27 representative induces the physician, the physician's staff, the pharmacists, and the
28

1 pharmacists staff to submit paperwork to overcome prior authorization or other
2 roadblocks to getting a prescription filled.

3 133. Janssen sales representatives were given lists of pharmacies and specialty
4 pharmacies in their area to induce with lunches, meals and gifts in order to get their
5 agreement to work collaboratively on the pull-through efforts. Janssen sales
6 managers tracked the efforts of sales representatives to call on the pharmacies with
7 inducements in order to establish the relationships, and to follow up with them to
8 get them to follow up on prior authorization paperwork from insurance companies
9 to get drug prescriptions approved.

10 134. At Olysio dinner speaker presentations in 2014-2015, Janssen employees
11 were instructed by Defendants' sales managers to invite sales representatives from
12 the specialty pharmacy that helped fill the Olysio prescriptions. These specialty
13 pharmacy sales representatives were also encouraging off-label discussions about
14 Olysio and the COSMOS study. The specialty pharmacy sales representatives were
15 much more aggressive in pushing off-label uses for Olysio to the doctors.
16 Accordingly, Janssen sales managers preferred to have specialty pharmacy sales
17 representatives attend their Olysio meetings.

18 135. For example, in October, 2014 a presentation was given at a Janssen meeting
19 for physicians at a Newport, California meeting by Rafael Marfil (See Exhibit 19).
20 Mr. Marfil was the Sendera pharmacy founder, and he expressed the critical nature
21 of the leverage between the representative and the pharmacy in order to pull
22 through the medication. In this presentation, the representative demonstrated that
23 when he has a difficult prescription (off-label prescription) to pull-through past the
24 insurance company prior-authorization obstacles, he calls the pharmacy where the
25 prescription is supposed to be fulfilled. The pharmacy then reached out to the
26 insurance company and had a variety of template studies that are attached to each
27 in order to obtain the prior authorization for each off-label prescription. This

1 relationship and collaboration is essential in procuring such a large percentage of
2 medications that are cost prohibitive and not on the drug formularies. This scheme
3 is similar to the off-label promotion scheme that was promoted for use by
4 Defendants' Olysio sales representative in February, 2015 as a "Success Story"
5 with Dr. Victor Machicao at the University of Texas for his liver transplant
6 patients with acid reflux problems (See Exhibit 20).

7 136. For example, in December, 2014, Janssen sales representatives were given
8 information from Defendants to provide to doctors promoting the use of Olysio
9 off-label for HIV, post-liver transplantation and renal failure patients. The
10 information was included in a Janssen letter to physicians which was supposed to
11 be used only for unsolicited requests for off-label information from physicians.
12 However, Defendants' District Managers routinely ordered sales representatives to
13 make available off-label information to hospitals and physicians in order to realize
14 a boost in sales, and in order to get Defendants' MSLs invited to give additional
15 off-label information to doctors promoting the use of Olysio for HIV and renal
16 failure patients (See Exhibit 21).

17 137. Janssen had established a "closed network" of specialty pharmacies for the
18 sale of the drug Simponi, and the Olysio sales force was instructed to use this
19 closed network for Olysio. Furthermore, the Olysio sales force was instructed to
20 nominate local specialty pharmacies for inclusion in the closed network.

21 138. For example, one Janssen sales and marketing document notes that the sales
22 representative worked closely with Janssen's Rich Appiah to get two local specialty
23 pharmacies approved for the Simponi closed network "which enables full portfolio
24 coverage with both Olysio & Simponi and expanded relationship and opportunity
25 for local area pharmacies" (See Exhibit 22).

26 139. For example, a Janssen sales and marketing email stated that Janssen had
27 speakers from Sendera Specialty Pharmacy come to a Janssen sales meeting to
28

1 train sales reps on collaborating more closely on pulling-through the Olysio
2 prescriptions (See Exhibit 23).

3 140. Janssen Senior Training Manager for Sales and Development, Policia Perez
4 instructed all sales representatives to collaborate with Medical Science Liaisons
5 (“MSLs”) to work on pull-through of the off-label Olysio prescriptions. MSLs
6 were Janssen employees who were supposed to respond to physician requests for
7 off-label information, but Janssen developed a scheme to use them as a more
8 aggressive part of the sales force and instructed sales representatives to set
9 meetings for them to promote off-label uses to pharmacy staff and physicians (See
10 Exhibit 24).

11 141. Janssen incentivized sales representatives to induce pharmacies and
12 specialty pharmacies to help with prescription pull-through. Nearly all Olysio sales
13 that were reported by specialty pharmacies were being "allocated" to the
14 responsible Janssen rep for commission credit.

15 142. For example, a November 2014 email among Olysio sales staff discussed the
16 allocation of Premier Specialty Pharmacy sales among local sales reps (See Exhibit
17 25).

18 *viii. Defendants sponsored seminars, symposia, and other continuing*
19 *medical education programs that promoted the off-label use of their*
20 *drugs*

21 143. Specifically, as part of its scheme to promote its opioid drugs Nucynta,
22 Nucynta ER, Ultram ER, and Duragesic, and its other drugs Olysio, Xarelto,
23 Aciphex, Levaquin, Remicade, Elmiron, Aciphex, Invokana, Simponi, Elmiron,
24 and Imbruvica, and other Defendants’ drugs widely for use to treat off-label patient
25 populations, Janssen sought out influential physicians and proffered kickbacks to
26 them in return for conducting research and implementing policies promoting the
27 use of Defendants’ drugs in those off-label cases. As set forth below, most of this

1 “research” consisted of paying a physician to prescribe Defendants’ opioid drugs
2 Nucynta, Nucynta ER, Ultram ER, and Duragesic, and its other drugs Olysio,
3 Xarelto, Aciphex, Levaquin, Remicade, Elmiron, Aciphex, Invokana, Simponi,
4 Elmiron, and Imbruvica, and other Defendants’ drugs and report some simple
5 findings. The Janssen marketing department made the decisions on which doctors
6 to pay to do case studies and be involved in research protocols based on their drug
7 prescribe volume, showing that Janssen was not paying those doctors for a
8 legitimate research purpose. In effect, Janssen paid these influential physicians to
9 prescribe their patients with Janssen drugs in order to expand its market share.
10 Janssen also paid these “Key Opinion Leaders” and “Champions” to promote the
11 use of opioid drugs Nucynta, Nucynta ER, Ultram ER, and Duragesic, and its other
12 drugs Olysio, Xarelto, Aciphex, Levaquin, Remicade, Elmiron, Aciphex,
13 Invokana, Simponi, Elmiron, and Imbruvica at seminars and other events for
14 referring cardiologists, clinic staff, and prescribing drugs in patients.

15 *ix. Defendants provided financing and other support for questionable*
16 *research to support and promote the use of their drugs in off-label*
17 *patient populations.*

18 144. Defendants engaged in a researching and publishing campaign under which
19 it paid physicians to engage in off-label studies of Olysio in HIV and renal failure
20 patients, and other uses, along with off-label uses of Levaquin, Xarelto, Nucynta,
21 and other Defendants’ drugs. These studies were heavily influenced by bias, since
22 the physicians were paid by Defendants; the research was often coordinated by
23 Defendants; and in many cases, Defendants’ employees were included as
24 researchers on the projects. In sum, Defendants deliberately pursued a scheme
25 under which they paid for biased research and studies to support the use of Olysio
26 off-label in HIV and renal failure patients, and other off-label uses for Levaquin,
27 Xarelto, Nucynta, and other Defendants’ drugs.

1 145. Defendants used a speaker program to promote the drug Elmiron. Notably,
 2 Defendants paid the developer of the drug, Dr. Lowell Parsons from San Diego, to
 3 appear as a promotional speaker. Dr. Parsons is not in-house at Janssen, so when
 4 he spoke at these paid events, he had the appearance of being a credible or neutral
 5 third party, when in fact he was making a speaker fee, and probably royalties from
 6 the sale of the drug.

7 146. Defendants also ran a number of nationwide studies which engaged a large
 8 number of investigators, each of whom enrolled a few patients each, and for which
 9 doctors were remunerated up to several thousand dollars per enrolled patient, in
 10 order to create brand loyalty with the physicians, often for off-label uses.

11 147. Defendants' research and publication campaign had a clear purpose: to
 12 support and promote the off-label use of Olysio for HIV and renal failure patients,
 13 and other off-label uses for Nucynta, Nucynta ER, Xarelto, Ultram ER, Duragesic,
 14 Aciphex, Levaquin, Remicade, Elmiron, Aciphex, Invokana, Simponi, Elmiron,
 15 Imbruvica, and other Defendants' drugs.

16 **B. Defendants Illegally Promoted Use of Their Drugs by Providing**
 17 **Kickbacks to Physicians and Researchers.**

18 148. Defendants used illegal kickbacks and quid pro quo arrangements to ensure
 19 that physicians would continue to prescribe Defendants' drugs. None of these
 20 incentives have anything to do with true scientific or medical research or with the
 21 safety of patients. These incentives include cash payments to "consultants" and
 22 "preceptors," cash payments for a "speaker's bureau" and to national and regional
 23 "advisory boards" and for participation in teleconferences, post-market research,
 24 "case studies," as well as the other activities described herein.

25 149. Advisory boards were completely overseen by Defendants' marketing
 26 department. Marketing would invite the speakers and nominate the members of the
 27 advisory boards. With Olysio for example, they met at least three (3) times a year,
 28

1 normally in Chicago and Los Angeles. Physician's travel was paid, and they were
2 paid for participating, at least \$1500.

3 150. Defendants rewarded doctors with many of these kickbacks for prescribing
4 large quantities of its opioid drugs Nucynta, Nucynta ER, Ultram ER, and
5 Duragesic, and its other drugs Olysio, Xarelto, Aciphex, Levaquin, Remicade,
6 Elmiron, Aciphex, Invokana, Simponi, Elmiron, and Imbruvica, and other
7 Defendants' drugs. Some doctors, who prescribed a large number of Defendants'
8 drugs, were given gifts including expensive meals. Defendants also expected sales
9 representatives to supply some doctors with wine and alcohol at dinner. Relator has
10 personal knowledge of alcohol provided at dinners.

11 151. Relator also has personal knowledge of at least one of the Defendants'
12 speaker program dinners at which some attendees used cocaine, as well as an
13 illegal sales and marketing scheme whereby physicians in the Korea Town area of
14 Los Angeles were frequently taken to a "spa" for prostitution services that were
15 paid for by Defendants' sales representatives using corporate credit cards and/or
16 other corporate entertainment funds. Relator was also aware of a physician in
17 Korea Town who was paid over \$100,000 by Defendants in 2009 for an office
18 remodeling project.

19 152. Defendants established formal internal guidelines for the award of these
20 benefits to physicians, in effect pushing "prescribe to play," quid pro quo-focused
21 sales strategies which are based entirely on the amount of prescriptions written by
22 the physicians and the ability of the physician to influence other physicians to
23 begin prescribing Defendants' drugs. The recipients of these awards and benefits
24 were selected by Defendant marketers based on the recipients' ability to prescribe
25 its opioid drugs Nucynta, Nucynta ER, Ultram ER, and Duragesic, and its other
26 drugs Olysio, Xarelto, Aciphex, Levaquin, Remicade, Elmiron, Aciphex,
27 Invokana, Simponi, Elmiron, and Imbruvica, and other Defendants' drugs, and to

1 influence other doctors to do so.

2 153. Some doctors demanded payment from Defendants as a speaker, a
3 researcher in order to use Defendants' drugs, or demanded Defendants pay for
4 lunch or dinner for the physicians' entire office or the physicians' friends.
5 Defendants' managers generally agreed to pay, and instructed sales representatives
6 to arrange the paid activity for the doctor. Defendants' sales representatives were
7 then responsible for following through to ensure that Defendants generated its
8 opioid drugs Nucynta, Nucynta ER, Ultram ER, and Duragesic, and its other drugs
9 Olysio, Xarelto, Aciphex, Levaquin, Remicade, Elmiron, Aciphex, Invokana,
10 Simponi, Elmiron, and Imbruvica, and other defendant drug sales based on the
11 provision of the quid pro quo payment.

12 154. Paid speakers received increasing amounts of money over time with Janssen,
13 starting from \$1,000 per talk in relator's early years with the company to \$3,000
14 per talk near the end. As long as the money was in the budget, Janssen pushed its
15 sales representatives to pay for speakers in order to entice them to prescribe more
16 drug.

17 155. As a result of this pressure and despite continual objections by Janssen sales
18 representatives that there were no additional **educational** needs in the market for
19 Olysio, the Janssen Regional Business Director and District Manager kept
20 continual tabs of speaker programs and measured how many speaker programs
21 each district or sales representative conducted. The sales representatives
22 continually echoed that, since the medication is no longer in the launch mode and
23 the majority of physicians are well trained, "there is no longer an educational need
24 for the dinners." Due to increasing management pressure and the deleterious
25 effects on employment, these dinners were conducted on nearly a weekly basis, in
26 an expensive restaurant to allure and entertain physicians.

27 156. Often the physicians attending were friends, colleagues or referral partners

1 and this was no more than a social event, an opportunity to have a referral dinner
2 and enjoy some entertainment provided to them by the Defendant.

3 157. For example, a speaker dinner with Dr. Edward Mena was held on
4 approximately Jan. 18th or 19th, 2015 at Hakafan restaurant in Beverly Hills, at a
5 program being run by Janssen sales rep Manisha Jaishangani. Relator was present,
6 and noted that Dr. Edward Mena had brought his manicurist girlfriend, and she was
7 eating and expensing it to Janssen. This was a violation of the Janssen policy on
8 not paying for girlfriends, wives and families of doctors. However, no one at
9 Janssen was allowed to tell a doctor that their family members had to leave a
10 meeting, so Dr. Mena's girlfriend was allowed to stay and eat and expense it to
11 Janssen.

12 158. To make matters worse, the Janssen Regional Business Director requested a
13 roster of favorability of speakers. This scoring system highlighted the physicians
14 who wrote a higher volume of prescriptions, and who spoke favorably about
15 various niches where they used the product. The sales representatives were
16 expected to use these physicians as speakers most frequently, and this speaker
17 program thereby provided a reward for their increased utilization. Those that were
18 strictly using Janssen drugs on-label were considered "neutral" or "unfavorable"
19 and the sales representatives were instructed to use them less often (See Exhibit 26,
20 27).

21 159. For example, a February 22, 2008 Janssen business plan said that Janssen
22 sales representatives were to "Target speaker programs for aciphex and levaquin
23 for highest opportunity physicians" (See Exhibit 28).

24 160. For example, an April 5, 2015 email promotes two physicians who are
25 Olysio speakers who show "Extensive experience with our regimen, and actively
26 prescribing to date" and are "passionate" advocates (See Exhibit 29).

27 161. Around December, 2014, Defendants' business conduct worsened when a

1 Janssen District Manager wrote a scathing internal Janssen email about a speaker's
2 presentation. The District Manager wrote about Dr. Sammy Saab, who was asked
3 at one Janssen sponsored dinner what his "go-to prescription" was. Dr. Saab
4 asserted that he uses competing drug Harvoni, and uses the combination as a
5 secondary agent (See Exhibit 30). The Janssen Regional Business Director then
6 requested that the Relator approach and shakedown the physician and confront him
7 by saying, "for someone that we have spent so much marketing money, why is he
8 writing so few scripts?" He further continued "if we are to continue using him he
9 would need to use our product extensively."

10 162. On the other hand, Defendants gave handsome rewards to doctors who
11 prescribed a high volume, and the sales representatives who worked with those
12 doctors.

13 163. Defendants' drug Aciphex was abused by sales representatives as part of a
14 sales scheme to get prescriptions paid for by insurance without even having actual
15 patients taking the drug. Doctors wrote prescriptions for patients who did not need
16 the drug. Janssen issued "7 day savings cards" to the sales representatives. The
17 reps took these cards, along with the patient prescriptions, to the pharmacy, got the
18 prescriptions filled, then delivered the filled prescriptions back to the doctors'
19 office. This was a way for reps to get huge sales numbers, and for the doctors to
20 get credit with Janssen, without patients ever having to pick up the drug. No
21 patients consented for this.

22 164. For example, Dr. Simon Chan had prescriptions for four thousand (4000)
23 Aciphex patients, a completely disproportional number to the size of his practice.
24 Many or most of these prescriptions were paid for by Medi-Cal. Sales
25 representative Amy Chun won a "President's Circle" award from Janssen because
26 her sales numbers were so high as a result of this scheme.

27 165. To build and maintain sales relationships, Defendants bought meals for
28

1 doctors and their staff. Dinners were about once per week; lunches were every day.
2 Most of the time, the restaurant would bring in the food, but sometimes the reps
3 had to bring in the food. A lot of the offices needed two different foods – kosher
4 for the doctors, and non-kosher for the staff. Offices were also brought ice cream,
5 pizza, breakfast, and other treats on a consistent basis (See Exhibit 31).

6 166. For example, from May 19, 2005 through October 13, 2005, Janssen
7 provided fifty-four (54) lunches and fifteen (15) dinners to doctors in the Cedars
8 territory, and paid three doctors as speakers to promote Aciphex and Levaquin (See
9 Exhibit 32).

10 167. For example, on March 25, 2013, Janssen paid \$134.82 for lunch for Dr.
11 James Jung's office from Chosun Galbee Restaurant in Los Angeles (See Exhibit
12 33).

13 168. For example, on April 2, 2013, Janssen paid \$69.26 for lunch for Dr.
14 Sharim's office from Shah Abbas Restaurant in Beverly Hills (See Exhibit 34).

15 169. For example, on March 29, 2013, Janssen paid \$79.97 for lunch for Dr.
16 Sharim's office from Beach House Restaurant in Hermosa Beach (See Exhibit 35).

17 170. For example, on March 26, 2013, Janssen paid \$66.63 for lunch for Dr.
18 Nassir's office from Real Food Daily Restaurant in Los Angeles (See Exhibit 36).

19 171. For example, on March 20, 2013, Janssen paid \$130.80 for lunch for Dr.
20 Nusinovich's office from Fresh Corn Grill Restaurant in West Hollywood (See
21 Exhibit 37).

22 172. For example, on March 12, 2013, Janssen paid \$260.38 for lunch for a
23 doctor's office from a restaurant in Los Angeles (See Exhibit 38).

24 173. For example, on November 2, 2011, Janssen paid \$138.59 for lunch for a
25 doctor's office from Shah Abba's Restaurant in Los Angeles (See Exhibit 39).

26 174. For example, on January 12, 2012, Janssen paid \$210.00 for lunch for a
27 doctor's office from Armai restaurant in Los Angeles (See Exhibit 39).

1 175. For example, on January 12, 2012, Janssen paid \$168.10 for lunch for a
2 doctor's office from Chicken Dijon restaurant in El Segundo (See Exhibit 39).

3 176. For example, on December 20, 2011, Janssen paid \$229.00 for lunch for a
4 doctor's office from Chicken Dijon restaurant in El Segundo (See Exhibit 39).

5 177. For example, on January 25, 2012, Janssen paid \$207.21 for lunch for a
6 doctor's office from Shah Abba's Restaurant in Los Angeles (See Exhibit 39).

7 178. For example, on February 2, 2012, Janssen paid \$194.00 for lunch for a
8 doctor's office from Shah Abba's Restaurant in Los Angeles (See Exhibit 39).

9 179. For example, on February 7, 2012, Janssen paid \$142.00 for lunch for a
10 doctor's office from Chicken Dijon restaurant in El Segundo (See Exhibit 39).

11 180. For example, on February 10, 2012, Janssen paid \$114.90 for lunch for a
12 doctor's office from Chicken Dijon restaurant in El Segundo (See Exhibit 39).

13 181. For example, on April 6, 2012, Janssen paid \$210.00 for lunch for a doctor's
14 office from Armai restaurant in Los Angeles (See Exhibit 39).

15 182. For example, on April 11, 2012, Janssen paid \$170.89 for lunch for a
16 doctor's office from Sharky's restaurant in Beverly Hills (See Exhibit 39).

17 183. For example, on April 27, 2012, Janssen paid \$150.95 for lunch for a
18 doctor's office from California Pizza Kitchen in Los Angeles (See Exhibit 39).

19 184. For example, on May 9, 2012, Janssen paid \$1,866.40 for dinner for a
20 doctor's office from Siene Bar and Grill restaurant in Beverly Hills (See Exhibit
21 39).

22 185. For example, on December 8, 2011, Janssen paid \$1,346.47 for dinner for a
23 doctor's office from Wolfgang's Steakhouse restaurant in Beverly Hills (See
24 Exhibit 39).

25 186. For example, on April 18, 2012, Janssen paid \$1,161.14 for dinner for a
26 doctor's office from Il Covo restaurant in Los Angeles (See Exhibit 39).

27 187. For example, and particularly, attached as an exhibit are photographs
28

1 illustrating some of the Defendants' speaker programs, the high usage of alcohol at
2 some of the Defendants' funded events, birthday parties for doctors and their
3 medical staff paid for by the Defendants, and catered lunches that Defendants'
4 employed for its high prescribing physicians and their medical staff, pharmacy,
5 hospital and other healthcare customers and Defendants' sales representatives to
6 induce them to prescribe its opioid drugs Nucynta, Nucynta ER, Ultram ER, and
7 Duragesic, and its other drugs Olysio, Xarelto, Aciphex, Levaquin, Remicade,
8 Elmiron, Aciphex, Invokana, Simponi, Elmiron, and Imbruvica (See Exhibit 40):

- 9 a. A photograph Defendants' funded speaker program and birthday cake
10 for Dr. Sammy Saab on or about November 18, 2014 to promote
11 Defendants' opioid drugs Nucynta, Nucynta ER and Ultram and its
12 other drugs;
- 13 b. A photograph from a typical Defendants' funded physician's dinner,
14 with sashimi bowl with caviar on or about July 25, 2013 to promote
15 Defendants' opioid drugs Nucynta, Nucynta ER, Ultram, Duragesic,
16 and its other drugs;
- 17 c. A photograph of deceased celebrity singer Michael Jackson's former
18 physician Dr. Allan Metzger with two Defendants' sales
19 representatives on or about November 16, 2011 to promote
20 Defendants' opioid drugs Nucynta, Nucynta ER, Ultram, Duragesic,
21 and its other drugs;
- 22 d. A photograph of Dr. Ed Kim with alcohol at a Defendants funded Dr.
23 Lawrence Miller speaker program on or about June 10, 2010 to
24 promote Defendants' opioid drugs Nucynta, Nucynta ER, Ultram,
25 Duragesic, and its other drugs;
- 26 e. A photograph of one of Defendants' targeted physician and his
27 medical staff with alcohol at the same Defendant's funded Dr.

1 Lawrence Miller's speaker program on or about June 10, 2010 to
2 promote Defendants' opioid drugs Nucynta, Nucynta ER, Ultram,
3 Duragesic, and its other drugs;

4 f. A photograph of a doctor with a Xarelto package on or about
5 December 6, 2012 during a Defendants' funded meeting to illegally
6 promote and market Xarelto and its other drugs. More specifically,
7 here, the physician is Dr. Mark Barats is a nephrologist at this Janssen
8 funded meeting where its drug Xarelto was not indicated for kidney
9 compromised patients;

10 g. A photograph of Dr. Peter Rosenberg's birthday cake on or about
11 November 17, 2014 to promote Defendants' opioid drugs Nucynta,
12 Nycunta ER, and Ultram, and its other drugs;

13 h. A photograph of a birthday party for a nurse at South Bay
14 Gastroenterology group on or about June 25, 2014, to promote
15 Defendants' opioid drugs Nucynta, Nycunta ER, and Ultram, and its
16 other drugs;

17 i. A photograph of a birthday party for a nurse at South Bay
18 Gastroenterology Medical Group on or about June 3, 2014, to promote
19 Defendants' drugs Olysio, Simponi, Remicade, and its other drugs;

20 j. A photograph of a birthday party for office staff at South Bay
21 Gastroenterology Medical group on or about May 24, 2011 to
22 promote Defendants' drugs Olysio, Simponi, Remicade, and its other
23 drugs;

24 k. A photograph of deceased celebrity singer Michael Jackson's former
25 physician Dr. Allan Metzger's assistant's birthday party at his office
26 on or about May 24, 2011 to promote Defendants' opioid drugs
27 Nucynta, Nycunta ER, Ultram, Duragesic, and its other drugs;

1 188. Defendants knew that its provision of kickbacks to these physicians and
2 researchers was illegal and made efforts to conceal its illegal, fraudulent scheme by
3 funneling some payments through third-party consulting organizations. Defendants
4 also understood that its provision of these kickbacks actually caused its opioid
5 drugs Nucynta, Nucynta ER, Ultram ER, and Duragesic, and its other drugs
6 Olysio, Xarelto, Aciphex, Levaquin, Remicade, Elmiron, Aciphex, Invokana,
7 Simponi, Elmiron, and Imbruvica to be used for off-label purposes. Many of these
8 drugs were paid for by Medicaid, Medicare, and the TRICARE health care system
9 for military members and their families. Had the United States and the several
10 States known that these drugs were used due to a fraudulent kickback scheme, they
11 would not have provided reimbursement for these drugs.

12 *i. Defendants Paid Physicians Honoraria, and Lavish Meals to Attend*
13 *or Speak at Events Promoting the Use of Opioid Drugs Nucynta,*
14 *Nucynta ER, Ultram ER, and Duragesic, along with Olysio, Xarelto,*
15 *Aciphex, Levaquin, Remicade, Elmiron, Aciphex, Invokana, Simponi,*
16 *Elmiron, and Imbruvica, and other Defendants' Drugs.*

17 189. In their efforts to promote the use of its opioid drugs Nucynta, Nucynta ER,
18 Ultram ER, and Duragesic, and its other drugs Olysio, Xarelto, Aciphex, Levaquin,
19 Remicade, Elmiron, Aciphex, Invokana, Simponi, Elmiron, and Imbruvica, and
20 other Defendants' drugs in off-label patient populations, Defendants provided
21 honoraria, and lavish meals to key opinion leaders and other physicians to attend or
22 speak at dinners, lunches, conferences, symposia, and other events where
23 Defendants' drugs were being promoted.

24 190. The meals directly took into account the volume and value of the business
25 generated and were given to physicians who had used or would agree to use or
26 promote the use of its opioid drugs Nucynta, Nucynta ER, Ultram ER, and
27 Duragesic, and its other drugs Olysio, Xarelto, Aciphex, Levaquin, Remicade,

1 Elmiron, Aciphex, Invokana, Simponi, Elmiron, and Imbruvica.

2 191. Many dinner meetings consisted of lavish dinners at local restaurants. The
3 emphasis at some of these meetings was also on off-label uses of its opioid drugs
4 Nucynta, Nucynta ER, Ultram ER, and Duragesic, and its other drugs Olysio,
5 Xarelto, Aciphex, Levaquin, Remicade, Elmiron, Aciphex, Invokana, Simponi,
6 Elmiron, and Imbruvica, and other Defendants' drugs, and thousands of dollars'
7 worth of honoraria were paid to physicians who spoke about off-label uses at these
8 meetings. High volume prescribing doctors and local opinion leaders were targeted
9 for invitation. High volume prescribing Medicaid and Medicare doctors were often
10 specifically targeted for invitation. At all of the events physicians were encouraged
11 to increase their use of Defendants' drugs.

12 192. For example, a February 12, 2015, dinner was held at the expensive
13 Cecconi's restaurant in West Hollywood, California for high prescriber Dr.
14 Edward Mena and for some other physicians who were targeted for sales (See
15 Exhibit 41).

16 193. Defendants ensured that cash and meals were often targeted specifically at
17 high Medicare and Medicaid prescribing doctors, to increase market share within
18 the Medicaid and Medicare programs, and to influence the market share status of
19 Defendants' drugs within the Medicaid and Medicare programs. In addition, cash
20 and meals were often targeted at high Medicaid and Medicare volume facilities in
21 order to increase Defendants' reimbursements through State and Federal health
22 care systems. Also, formulary committee members at high volume Medicaid
23 facilities were specifically targeted for cash and meals to place Defendants' drugs
24 on their approved drug formularies and hospital protocols, and to purchase
25 Defendants' drugs for their inventories and increase Janssen's reimbursements.

26 194. Defendants' sales representatives were encouraged to be involved with prior
27 authorization process with Ultram ER, Nucynta, Nucynta ER, Aciphex and

1 Simponi in order to pass insurance, hospital and Medicare drug formularies, and
2 prior authorization manipulation was part of their business plans (See Exhibit 42).
3 Not only does this violate HIPAA, it also violates prohibitions on illegal
4 kickbacks.

5 195. During 2009 and from 2012-2015, Relator was on Defendants' sales force
6 for selling the drug Remicade. Janssen managers required Relator to induce staff at
7 RxBiotech specialty pharmacy located in the Beverly Sinai Medical Pharmacy
8 with lunches and dinners and other inducements to get them to give access to lists
9 of patient names, and to pull-through Remicade prescriptions, using Janssen-
10 created language to present to insurance payers in order to get Remicade
11 prescriptions approved through prior authorization.

12 196. Defendants' District Managers touted that the number one sales
13 representative in the country in 2012 got prescriptions by going to physician
14 offices and simply flagging the charts with Ultram ER stickers and doing prior
15 authorizations for each patient. This practice was encouraged by the Regional
16 Business Director and other District Managers. Examples of prior authorization
17 pull through effort requirements for sales staff by District Manager Mo Issa are
18 added as an Exhibit. (See Exhibit 43).

19 197. Defendants' sales representative involvement in the prior authorization
20 process endangered the patients' HIPAA rights and was designed to bypass the
21 existing formulary process to gain the prescription.

22 198. Janssen's territory business plans often included tracking of doctors by their
23 volume of Medicare and Medicaid patients, average duration of treatment, and the
24 average revenue from Janssen drugs. Janssen management utilized this Medicaid
25 and Medicare volume information in order to determine which doctors to target for
26 expensive meals and cash payments.

27 199. For example, a February 27, 2015, Janssen business email updated Olysio
28

1 sales representatives about various State Medicaid agreements to pay for the drug.
2 Medicaid programs in California and a large number of other states were covering
3 Olysio as of Feb. 25, 2015, and Janssen tracked twenty-three (23) states where
4 Medicaid payment was possible. Janssen sales representatives were sent the
5 information by email, and were told to report on their experience in “pulling
6 through” any of the California Medicaid prescriptions through the California prior
7 authorization process (See Exhibit 44).

8 200. For example, a 2009 sales planning spreadsheet called for offering paid
9 speaker programs and paid lunches as part of the “Plan of Action” to get Medicare
10 and private insurance reimbursed physicians to write more prescriptions for
11 Nucynta (See Exhibit 45).

12 201. For example, an August 3, 2014, Janssen business plan document called for
13 offering paid speaker programs and paid lunches as part of a campaign to promote
14 Olysio to Medicare physicians. The document noted that Dr. John Hoefs had 10%
15 Medicare patients; the office of Dr. Tarek Hassanein had 32% Medicaid and 10%
16 Medicare; Dr. Richard Quist had 9% Medicare; Dr. Michael Demicco had 16%
17 Medicare; Dr. Ke-Qin Hu had 67% Medicare; the office of Dr. Alaa Abousaif had
18 6% Medicare; Dr. Syam Gaddam had 13% Medicare; and Dr. Lawrence Hurwitz
19 had 10% Medicare (See Exhibit 42).

20 202. For example, a June 9, 2013 Janssen sales tracking document for Ultram ER
21 noted that 21% of sales were to Medicare patients, and 4% were to Medicaid fee-
22 for-service patients (See Exhibit 46).

23 203. Defendants’ sales representatives were instructed to coordinate checks for
24 payment for up to \$3,000 to speakers for each dinner speaking program, and
25 invitations to lavish meals exclusively to targeted high volume prescribers or
26 referral sources in order to meet the sales representatives’ required sales levels for
27 bonus payouts each quarter. Defendants’ sales representatives were instructed to
28

1 target cardiologists, catheterization lab physicians, and internal medicine
2 physicians for prescriptions, and buy them expensive meals, and sign them up for
3 paid speaking engagements.

4 204. For example, on January 27, 2012, Dr. Gerald Sacks was paid \$1,500 to
5 speak at Boa Steakhouse in West Hollywood, California on the topic of
6 management of chronic pain to promote the Janssen opioid Nucynta (See Exhibit
7 47).

8 205. For example, on February 6, 2012, Dr. Lawrence Miller was paid \$1,000 to
9 speak at Sotto Restaurant in Los Angeles, California on the topic of management
10 of chronic pain to promote the Janssen opioid Nucynta (See Exhibit 48).

11 206. For example, on March 18, 2008, Dr. Ellie Goldstein was paid \$1,500 to
12 speak at Valentino's Restaurant in Los Angeles, California on the topic of
13 community-acquired pneumonia to promote the Janssen antibiotic Levaquin (See
14 Exhibit 49).

15 207. For example, on May 9, 2012, Dr. Jonathan Nissanoff was paid \$2,500 to
16 speak at La Seine Restaurant in Beverly Hills, California on the topic of
17 management of chronic pain to promote the Janssen opioid Nucynta (See Exhibit
18 50).

19 208. For example, on March 7, 2012, Dr. William French was paid \$2,000 to
20 speak at Fig and Olive Restaurant in Los Angeles, California on the topic of stroke
21 and systemic embolism to promote the Janssen blood thinner Xarelto (See Exhibit
22 51).

23 209. For example, on June 27, 2012, Dr. Matthew Budoff was paid \$2,000 to
24 speak at Tanino Restaurant in Los Angeles, California on the topic of stroke and
25 systemic embolism to promote the Janssen blood thinner Xarelto (See Exhibit 52).

26 210. For example, on December 8, 2011, Dr. Lawrence Miller was paid \$1,000 to
27 speak at Boa Steakhouse in West Hollywood, California on the topic of
28

1 management of chronic pain to promote the Janssen opioid Nucynta (See Exhibit
2 53).

3 211. For example, on September 18, 2008, Dr. Allan Metzger was paid \$1,000 to
4 speak at Geisha House in Los Angeles, California on the topic of management of
5 chronic pain to promote the Janssen opioid Nucynta (See Exhibit 54).

6 212. For example, on October 21, 2008, Dr. Gerald Sacks was paid \$1,500 to
7 speak at Katana Restaurant in West Hollywood, California on the topic of "New
8 Directions in Pain" to promote the Janssen opioid Nucynta (See Exhibit 55).

9 213. For example, on April 18, 2012, Dr. Lawrence Miller was paid \$1,000 to
10 speak at IL Covo Restaurant in Los Angeles, California on the topic of
11 management of chronic pain to promote the Janssen opioid Nucynta (See Exhibit
12 56).

13 214. For example, on December 8, 2011, Dr. Lawrence Miller was paid \$1,000 to
14 speak at Wolfgang's Steakhouse in Beverly Hills, California on the topic of
15 management of chronic pain to promote the Janssen opioid Nucynta (See Exhibit
16 57).

17 215. Payment for dinner and other incentives to increase referrals to a physician
18 for the use of opioid drugs Nucynta, Nucynta ER, Ultram ER, and Duragesic, and
19 its other drugs Olysio, Xarelto, Aciphex, Levaquin, Remicade, Elmiron, Aciphex,
20 Invokana, Simponi, Elmiron, and Imbruvica, and other Defendants' drugs is
21 inappropriate and illegal. According to the federal Health and Human Services
22 Office of the Inspector General (HHS OIG), paid meals would be inappropriate if
23 they are tied directly or indirectly to the generation of federal health care program
24 business for the manufacturer, or for the purposeful inducement of business. See,
25 e.g., 68 F.R. 23738. ("these arrangements [entertainment, recreation, travel, meals,
26 etc.] potentially implicate the anti-kickback statute if any one purpose of the
27 arrangement is to generate business.")

ii. Defendants Concealed Some Illegal and Fraudulent Payments to Physicians by Funneling Them through Third Party Consultant Companies.

216. In order to hide illegal payments to physicians, Defendants made many payments to doctors through the MedForce marketing company, among other similar vendors. MedForce arranged for expensive meals and sent payments to sales representatives to be given to speakers for promoting Defendants' drugs off-label.

217. For example, Janssen contracted with MedForce to pay a speaker fee and set up invitations and dinner reservations for Dr. Edward Mena to speak at Cecconi's restaurant in West Hollywood, California on February 12, 2015 on Olysio. MedForce provided sign-in sheets for guests, reviewed unauthorized charges on the food and beverage bill, collected meeting evaluations, and provided a credit card authorization for expenses (See Exhibit 58).

iii. Defendants Knew Their Payments to Physicians Were Illegal Because They Were Intended for the Purposeful Inducement of Business.

218. Defendants knew their payments to physicians were illegal kickbacks. In fact, Defendants provided personnel with guidelines that indicated that field employees could occasionally provide modest meals or snacks to health care professionals where the primary purpose is an informational presentation (See Exhibit 59). In contrast, Defendants' dinner events with paid speakers were often a sham, with the speaker getting paid up to \$3,000 per speaking event, but having no real responsibility. Doctors received prepared slides from Defendants to speak from, so that the doctors did not have to put forth any effort to prepare a presentation, but gave the impression to attendees that the slides reflected their own opinions and conclusions. Doctors sometimes simply opened a laptop on the

1 table at dinner with some slides on it, and then only spoke for five to ten minutes,
 2 or did not speak at all and simply enjoyed the lavish dinner with the other
 3 attendees.

4 *iv. Defendants' Payment of Illegal Kickbacks to Physicians Actually*
 5 *Affected the Use of Opioid Drugs Nucynta, Nucynta ER, Ultram ER,*
 6 *and Duragesic, along with Olysio, Xarelto, Aciphex, Levaquin,*
 7 *Remicade, Elmiron, Aciphex, Invokana, Simponi, Elmiron, and*
 8 *Imbruvica, and other Defendants' Drugs among Doctors*

9 219. Defendants' scheme to pay physicians resulted in specific sales. Defendants,
 10 like most branded drug companies, monitor the relationship of its sales to its
 11 promotional efforts over a very short timeframe; Defendants would be concerned
 12 about a drop in sales within a certain therapeutic regime not after a year look-back,
 13 or even a quarterly look-back, but over a period of just weeks.

14 220. Defendants' marketing and sales strategy documents show that at least on a
 15 weekly basis Defendants were tracking prescription volume by doctor, and
 16 tracking the percentage change in prescribing habits of physicians for Defendants'
 17 drugs. In addition, Defendants tracked the return on investment ("ROI") of paid
 18 travel and expensive meals for physicians. Defendants' sales representatives were
 19 instructed to ask physicians for additional prescriptions when the physicians were
 20 paid to speak at a lavish meal event, and told to track follow-up prescriptions by
 21 the physician, and to hold the physicians accountable if the physicians did not
 22 increase prescriptions of Defendants' drugs.

23 221. Physicians were made aware by sales representatives that the physicians
 24 would not continue to be invited to lavish meals if the physicians did not remain in
 25 the high volume prescriber range, and if the physicians did not prescribe
 26 Defendants' drugs. Physicians who did not continue to prescribe Defendants' drugs
 27 were tracked on a quarterly basis by Defendants' marketing and sales personnel,
 28

1 and were sometimes penalized by being taken off target lists for invitations to
2 future lavish meals and offers of speaking engagements, paid research
3 opportunities, and other perks. Defendants' pushed "prescribe to play," quid pro
4 quo-focused sales strategies, which are based entirely on the amount of
5 prescriptions written by the physicians and the ability of the physician to influence
6 other physicians to begin prescribing Defendants' drugs. The recipients of these
7 awards and benefits were selected by Defendants' marketers based on the
8 recipients' ability to prescribe its opioid drugs Nucynta, Nucynta ER, Ultram ER,
9 and Duragesic, and its other drugs Olysio, Xarelto, Aciphex, Levaquin, Remicade,
10 Elmiron, Aciphex, Invokana, Simponi, Elmiron, and Imbruvica, and other
11 Defendants' drugs and to influence other doctors to do so.

12 222. Defendants' sales representatives provided meals and other favors for
13 physician members of formulary committees and of hospital guideline committees
14 and their staffs, including committees which affected large Medicaid and Medicare
15 patient populations, such as hospitals with large Medicaid and Medicare
16 populations. Defendants' management directed sales staff to invite formulary
17 committee members and guideline committee members to lavish meals and offer
18 paid speaking opportunities, paid research, and other perks. Defendants'
19 management arranged inducements for influential formulary and guideline
20 committee members in order to put its opioid drugs Nucynta, Nucynta ER, Ultram
21 ER, and Duragesic, and its other drugs Olysio, Xarelto, Aciphex, Levaquin,
22 Remicade, Elmiron, Aciphex, Invokana, Simponi, Elmiron, and Imbruvica, or
23 other Defendants' drugs on their formulary or guidelines or standing orders, or to
24 purchase Janssen drugs into inventory.

25 223. Defendants also instructed physicians' office staff and clinic personnel to
26 maximize Medicaid and Medicare billing. Defendants' field sales representatives
27 gave billing seminars, and paid billing maximization speakers to give

1 presentations, in which the Defendants' sales representatives suggested how to bill
2 Medicare in order to receive maximum revenues. The field sales representatives
3 also reviewed prior billings for some facilities, and suggested additional billings
4 that Medicaid or Medicare were known to pay for without question (See Exhibit
5 60).

6 224. Defendants also instructed its sales representatives to review patient records
7 at doctor's offices and to help them select high risk patients to receive opioid drugs
8 Nucynta, Nucynta ER, Ultram ER, and Duragesic, and its other drugs Olysio,
9 Xarelto, Aciphex, Levaquin, Remicade, Elmiron, Aciphex, Invokana, Simponi,
10 Elmiron, and Imbruvica, and other Defendants' drugs instead of competitor drugs.

11 225. For example, in 2014, the Janssen Specialty Hepatology and Immunology
12 ("JSHI") organization was brought together by Defendants for one purpose and
13 one purpose only: to exploit the short off-label niche in which the Olysio product
14 could be effectively marketed. To the tune of \$2.5 billion dollars in revenue (\$600
15 average price per pill) and the expense of Medicaid, Medicare, TriCare, and private
16 insurance companies this strategy was extremely successful. Soon after this off-
17 label opportunity closed, the company disbanded the JSHI franchise, as the
18 commercial opportunity for on-label sales of Olysio was considered minimal.

19 226. The evidence points to willful and premeditated schemes of off-label
20 promotion, kickbacks, and violations of patients' HIPAA protections. The Relator,
21 who was vocal about these tactics, was prevented from promotions and from
22 applying to other sales opportunities within the company, and was many times
23 verbally and publicly reprimanded for not toeing the company line, and generally
24 not being "positive."

25 227. The company was so aggressive about exploiting this Olysio off-label
26 opportunity that many times the reps were worked one hundred (100) hours per
27 week just to meet the extensive demands. Often times sales representatives were
28

1 required to work nights and weekends and to take very minimal vacations to meet
 2 the increased demand of this short window of Olysio's off-label sales
 3 "opportunity."

4 228. For example, in December 2014, Janssen Regional Business Director
 5 requested Defendants' sales representatives to participate in non-educational
 6 events such as a liver foundation "Healthy Flavors of Coronado Culinary Gala" in
 7 San Diego's prestigious Coronado Hotel, where high prescribing physicians were
 8 presented with an honorary plaque and award and Janssen paid \$4,000 to
 9 participate as a "Table Sponsor." The Coronado Hotel event violated company
 10 policy since it was only for the entertainment of Janssen's physician customers,
 11 and had no educational component. The decision to fund the event was based on
 12 Janssen Regional Business Director Mo Issa wanting to support a local San Diego
 13 customer, high-Olysio prescriber Dr. Tarek Hassanein, and the purpose was a quid
 14 pro quo arrangement with him for more prescribing (See Exhibits 61, 62).

15 **C. Defendants Illegally Promoted Use of Opioid Drugs Nucynta, Nucynta**
 16 **ER, Ultram ER, and Duragesic, along with Olysio, Xarelto, Aciphex,**
 17 **Levaquin, Remicade, Elmiron, Aciphex, Invokana, Simponi, Elmiron,**
 18 **and Imbruvica, and other Drugs by Illegally Promoting a Spread**
 19 **between Published Pricing and the Prices Offered to Customers.**

20 229. Defendants defrauded the Medicaid program by reporting excessively high
 21 and false prices for some of their prescription drugs with knowledge that Medicaid
 22 used these reported prices for establishing reimbursement to its Medicaid providers
 23 for these drugs. As a result, Medicaid sustained significant losses to its program by
 24 making reimbursement payments to Defendants' Customers/Medicaid providers
 25 for the drugs at illegally excessive prices compared to the prices at which the
 26 Defendants' Customers/Medicaid providers actually acquired the same drugs. This
 27 is a practice known in the industry as "creating a Spread." The Spread is utilized
 28

1 by pharmaceutical companies to seize market share and thereby to fraudulently
2 increase their profits.

3 230. Via this scheme, commencing sometime by at least 2005 and continuing
4 through the present, Defendants defrauded States and the United States by
5 knowingly causing the Medicaid Programs to pay false or fraudulent claims.
6 Examples of the Defendants' specific drug products at issue include its opioid
7 drugs Nucynta, Nucynta ER, Ultram ER, and Duragesic, and its other drugs
8 Olysio, Xarelto, Aciphex, Levaquin, Remicade, Elmiron, Aciphex, Invokana,
9 Simponi, Elmiron, and Imbruvica, and are identified by "NDC" numbers in
10 Relator's extensive documentary evidence. The drugs at issue are referred to
11 jointly as the "Spread Drugs."

12 231. The Defendants marketed and sold their Spread Drugs to their Customers.
13 The Customers purchased the Spread Drug products either directly from
14 Defendants, through a GPO contract, or through wholesalers or specialty
15 distributors. When Defendants sold their Spread Drugs to wholesalers, they
16 invoiced wholesalers at gross prices which Defendants referred to as wholesale
17 acquisition cost prices, however Defendants reported misleading, inflated AWP's
18 and, in some cases, WACs to the pricing compendia for the Spread Drugs which
19 had no relation to the prices Defendants knew were generally and currently
20 available in the marketplace.

21 232. The amount paid by a Customer was typically based on a price negotiated
22 with Defendants, a price negotiated with a GPO, or an often equally competitive
23 price set by a specialty wholesaler or distributor. Defendants offered "contract
24 pricing" to many of their Customers that was less than "Non-Contract" or "Regular
25 Cost" prices generally offered by wholesalers and distributors to any customer.
26 Defendants created inflated Spreads on the Spread Drugs for Customers that
27 purchased the Spread Drugs at regular cost, available to virtually any industry

1 customer, and an even greater Spread for those purchasing the Spread Drugs
2 “under contract”.

3 233. Regardless of the method of purchase, Defendants’ Customers submitted
4 claims for payment to Medicaid when a drug product was dispensed to a program
5 beneficiary. The claims submitted by Defendants’ Customers were paid at amounts
6 directly influenced by Defendants’ false and fraudulent prices. Defendants
7 disseminated false pricing information for their drug products to the Pricing
8 Publications. Defendants knew the prices they reported to the pricing compendia
9 controlled the pricing compendia’s published reports of AWP and WAC.

10 234. The manufacturers control the prices that are reported by the compendia,
11 including First DataBank (FDB) a Division of the Hearst Corporation. Some state
12 Medicaid programs use FDB. For example, FDB asserts that all pricing
13 information is supplied and verified only by the products’ manufacturers, and that
14 there is no independent review of those prices for accuracy.

15 235. Accordingly, the manufacturers functionally control what price information
16 that payors, including the Medicaid program, can obtain. Defendants have taken
17 undue advantage of the resulting disparity in status, power and knowledge by
18 knowingly reporting prices for Medicaid reimbursement purposes that bear no
19 relationship whatsoever to prices generally or currently available in the
20 marketplace. The Defendants knew that the state Medicaid programs, which
21 employ small numbers of pharmacy staff, would not have the manufacturers’
22 insider knowledge, resources, or opportunity necessary to discover and remedy the
23 Defendants’ drug pricing fraud.

24 236. Defendants first reported false prices for the Spread Drugs sometime by at
25 least 2005. The reported prices did not represent prices actually being charged in
26 the marketplace. Thereafter, Defendants’ employees typically reported and/or
27 confirmed the false and fraudulent prices to the Pricing Publications periodically.

1 During the relevant time period, Defendants generally reported falsely inflated
2 AWP and WACs on the Spread Drugs while simultaneously offering dramatically
3 lower prices to their Customers in the marketplace. Defendants routinely failed to
4 update, adjust, decrease or correct their initial price reports for the Spread Drugs to
5 reflect prices being charged in the marketplace. Consequently, Defendants caused
6 the price reporting compendia to publish false inflated WACs and/or AWP from
7 sometime by at least 2005 and continuing through the present.

8 237. Defendants knew that the prices they reported to the Price Publications
9 directly affected reimbursement amounts paid by the Medicaid Programs. The false
10 prices Defendants reported to the Pricing Publications caused inflated government
11 reimbursement amounts to be paid on claims submitted by Defendants' payors for
12 the drug products at issue. Additionally, Defendants knew that withholding reports
13 of WAC to the pricing compendia during the relevant time period would ensure the
14 pricing compendia's failure to report WAC. Relator's extensive documentary
15 evidence includes a pricing chart illustrating multiple examples of the NDCs at
16 issue showing: reported prices (AWP and, if applicable, WAC), the Relator's Cost
17 and the corresponding Spreads (difference between the prices at which Defendants
18 actually sold their Spread Drugs and the false prices reported by Defendants). The
19 prices listed as those available to the Relator, as an independent pharmacy, are
20 some of the highest prices offered by Defendants in the marketplace. Therefore,
21 the inflated Spreads available to the Relator were some of the lowest Spreads in the
22 marketplace.

23 238. Defendants manipulated AWP and WACs to induce their Customers to
24 purchase Defendants' Spread Drugs by marketing to their Customers the huge
25 profits that would result to them from excessive reimbursement payments.
26 Defendants actively used the inflated Spreads and huge profits as a marketing tool
27 directed at providers to promote increased sales of the Spread Drugs. Moreover,
28

the Spreads, in effect, marketed themselves. Any purchaser could easily calculate the potential profit by using the reported prices and the actual sales price. For example, the inflated Spreads were readily apparent from information on the drug purchasing software programs available to Customers from drug wholesalers.

239. The Defendants reported or caused to be reported false or misleading prices to Medicaid by providing false or misleading price information including but not necessarily limited to AWP, Suggested Wholesale Price ("SWP"), CDP, WAC, DP, List Price and direct wholesale price to the compendia with knowledge that they in turn would utilize such false and misleading price information in determining the AWP and DP that were reported to Medicaid.

240. For example, Defendants published AWP that were many times greatly in excess of 30% above acquisition price for the drugs, creating a large spread that was promoted to customers as a way of illegally profiting off of Medicaid (Exhibit 63):

Fill Date	Drug Name	NDC	AWP	Acquisit ion Cost	AWP \$ Spread	AWP % Spread
2/7/2011	LEVAQUIN 750MG (PREMIX)	50458- 0166-01	\$145.42	\$3.92	\$141.50	3609.69 39%
3/8/2010	LEVAQUIN 500MG/D5 W 100ML	50458- 0168-01	\$219.12	\$5.91	\$213.21	3607.61 42%
5/21/2010	LEVAQUIN 500MG/D5 W 100ML	50458- 0168-01	\$273.90	\$7.39	\$266.51	3606.35 99%

Fill Date	Drug Name	NDC	AWP	Acquisit ion Cost	AWP \$ Spread	AWP % Spread
10/25/2010	LEVAQUIN 500MG/D5 W 100ML	50458- 0168-01	\$109.56	\$2.96	\$106.60	3601.35 14%
5/12/2010	LEVAQUIN 500MG/D5 W 100ML	50458- 0168-01	\$136.95	\$4.43	\$132.52	2991.42 21%
2/5/2010	LEVAQUIN 750MG (PREMIX)	50458- 0166-01	\$242.36	\$7.84	\$234.52	2991.32 65%
6/21/2010	LEVAQUIN 750MG (PREMIX)	50458- 0166-01	\$242.36	\$7.84	\$234.52	2991.32 65%
9/7/2010	LEVAQUIN 750MG (PREMIX)	50458- 0166-01	\$242.36	\$7.84	\$234.52	2991.32 65%
11/2/2010	LEVAQUIN 750MG (PREMIX)	50458- 0166-01	\$60.59	\$1.96	\$58.63	2991.32 65%
1/31/2011	LEVAQUIN 750MG (PREMIX)	50458- 0166-01	\$60.59	\$1.96	\$58.63	2991.32 65%
2/28/2011	LEVAQUIN 750MG (PREMIX)	50458- 0166-01	\$363.54	\$11.76	\$351.78	2991.32 65%

Fill Date	Drug Name	NDC	AWP	Acquisit ion Cost	AWP \$ Spread	AWP % Spread
3/5/2011	LEVAQUIN 750MG (PREMIX)	50458- 0166-01	\$363.54	\$11.76	\$351.78	2991.32 65%
8/27/2010	LEVAQUIN 750MG (PREMIX)	50458- 0166-01	\$302.95	\$9.80	\$293.15	2991.32 65%
2/8/2010	LEVAQUIN 500MG/D5 W 100ML	50458- 0168-01	\$182.60	\$5.91	\$176.69	2989.67 85%
3/1/2010	LEVAQUIN 500MG/D5 W 100ML	50458- 0168-01	\$182.60	\$5.91	\$176.69	2989.67 85%
1/15/2011	LEVAQUIN 500MG/D5 W 100ML	50458- 0168-01	\$182.60	\$5.91	\$176.69	2989.67 85%
9/27/2010	LEVAQUIN 500MG/D5 W 100ML	50458- 0168-01	\$273.90	\$8.87	\$265.03	2987.93 69%
10/1/2010	LEVAQUIN 500MG/D5 W 100ML	50458- 0168-01	\$273.90	\$8.87	\$265.03	2987.93 69%
10/11/2010	LEVAQUIN 500MG/D5 W 100ML	50458- 0168-01	\$273.90	\$8.87	\$265.03	2987.93 69%

Fill Date	Drug Name	NDC	AWP	Acquisit ion Cost	AWP \$ Spread	AWP % Spread
10/14/2010	LEVAQUIN 500MG/D5 W 100ML	50458- 0168-01	\$45.65	\$1.48	\$44.17	2984.45 95%
1/25/2011	LEVAQUIN 500MG/D5 W 100ML	50458- 0168-01	\$91.30	\$2.96	\$88.34	2984.45 95%
2/25/2011	LEVAQUIN 500MG/D5 W 100ML	50458- 0168-01	\$91.30	\$2.96	\$88.34	2984.45 95%
2/28/2011	LEVAQUIN 500MG/D5 W 100ML	50458- 0168-01	\$91.30	\$2.96	\$88.34	2984.45 95%
3/7/2011	LEVAQUIN 500MG/D5 W 100ML	50458- 0168-01	\$91.30	\$2.96	\$88.34	2984.45 95%
3/15/2011	LEVAQUIN 500MG/D5 W 100ML	50458- 0168-01	\$91.30	\$2.96	\$88.34	2984.45 95%
6/13/2011	LEVAQUIN 750MG (PREMIX)	50458- 0166-01	\$174.48	\$5.88	\$168.60	2867.34 69%
11/23/2010	LEVAQUIN /D5W 500/100 INJ	50458- 0168-01	\$482.02	\$75.37	\$406.65	539.538 3%

Fill Date	Drug Name	NDC	AWP	Acquisition Cost	AWP \$ Spread	AWP % Spread
11/26/2010	LEVAQUIN /D5W 500/100 INJ	50458- 0168-01	\$482.02	\$75.37	\$406.65	539.538 3%
11/29/2010	LEVAQUIN /D5W 500/100 INJ	50458- 0168-01	\$482.02	\$75.37	\$406.65	539.538 3%

241. Defendants were well aware of how Medicaid used Defendants' reported pricing information to set reimbursement levels to providers for the Spread Drugs. At all relevant times, Defendants were aware that Medicaid used published AWP's and/or WACs to estimate acquisition costs, defined as the best estimate of the price generally and currently paid by providers in the marketplace.

242. Defendants were also aware that the extraordinarily high volume of prescriptions processed by Medicaid requires the type of electronic data interchange that the Defendants have taken advantage of in order to defraud the Medicaid program. For example, from 2003 through 2011 Medicaid paid for an average of 35.8 million prescriptions per week nationwide. During this time, Medicaid processed prescriptions for over 35,000 NDC drug codes each year, reaching a peak of 39,212 NDC drug codes in 2011.

243. Defendants pay the Medicaid rebates and have reports that indicate the amount of their Spread Drugs, and the number of prescriptions for their Spread Drugs paid for by State by quarter. Defendants know that the Medicaid States are processing so many claims that it cannot be handled manually. Defendants know that Medicaid used complicated electronic payment databanks, and Defendants provided the databanks with false information.

1 244. After creating price Spreads for their Spread Drugs, Defendants enlarged
2 those Spreads by reducing acquisition costs to providers without disclosing the
3 reductions to compendia such as First DataBank or to the Medicaid Program.
4 Defendants also gave Customers incentives that decreased the price of prescription
5 drugs, such as discounts, rebates, off-invoice pricing, free goods, charge backs,
6 volume discounts, credit memos, “consulting” fees, debt forgiveness, educational
7 and promotional grants, and other financial incentives. Price reductions were
8 granted to some retail pharmacy chains, wholesalers, buying groups, pharmacy
9 benefit managers at the request of those chains, wholesalers, buying groups or
10 pharmacy benefit managers. These price reductions financially benefitted
11 providers, but were not reflected in the AWP’s and other price quotes the
12 Defendants reported to the compendia, which formed the basis for reimbursements
13 by Medicaid.

14
15 **DEFENDANT’S ACTS OF RETALIATION**

16 245. In early 2013, Relator was a celebrated company employee who had won
17 numerous sales awards from Defendants such as the “President’s Circle” for
18 highest national sales. Relator celebrated with Defendants’ employees on stage
19 with sales managers Russ Stough (Regional Business Director, Southern
20 California), Karen Martin, Molly Laughlin, Danielle Felter (District Manager,
21 Southern California), and Jason Hammond (District Manager, Southern California)
22 (please see photograph attached as Exhibit 64).

23 246. In or about November 2013, Relator became aware that there were
24 company-wide problems with off-label promotion and kickbacks.

25 247. The manner in which Defendants market the use of their drugs is governed
26 by the Food, Drug and Cosmetic Act (“FDCA”) (Title 21, U.S.C. § 355) and
27

1 inducements to physicians are covered by the Medicare and Medicaid anti-
2 kickback laws, 42 U.S.C. 1320a-7b(b), *et seq.*

3 248. In order to comply with the relevant laws and regulations, pharmaceutical
4 companies like Janssen must be able to account for all off-label marketing
5 materials and inducements given to physicians. In or about November 2013,
6 Relator found out that there were company-wide irregularities with respect to
7 tracking these payments and marketing materials. In particular, Relator spoke up at
8 the Newport meeting in December, 2014 with other Janssen sales representatives,
9 saying that with respect to the specialist pharmacies, that there was a question of
10 how was it legal for the company to work with the specialist pharmacies at such an
11 intimate level on prior authorization pull-through in order to forward the off-label
12 Olysio marketing scheme. At that time the Regional Director Mohammed Issa said,
13 in front of the other sales representatives, that “this was the biggest bunch of BS
14 that I’ve ever heard,” and then castigated Relator on multiple occasions for “not
15 being positive.” and “not being a team player,” and not “being flexible.”
16 Subsequently, the Regional Director warned Relator not to make the same
17 statements again.

18 249. Thereafter, Relator complained and reported to Janssen human resources and
19 management, both orally and in writing, of these alleged illegal business practices,
20 which violated the FDCA and Medicare and Medicaid anti-kickback laws and
21 other relevant statutes and regulations.

22 250. In retaliation for these actions, Relator’s supervisor at Janssen and Janssen
23 HR personnel began a campaign to harass and intimidate Relator. In particular, the
24 Regional Director would tell Relator that “you are not a team player,” and that
25 “you should not point this stuff out in front of the team.” This in spite of the fact
26 that in addition to driving five (5) to six (6) hours per day in Relator’s own
27 territory to manage the Los Angeles territory, which was the eleventh (11th) highest

1 volume territory in the nation, and managing a district including five (5) Western
2 States, Relator was accused of “not being flexible or a team player.” During this
3 time period, the relator worked in excess of one hundred (100) hours a week, and
4 consequently started to suffer many job-related physical and health complications
5 [with long-term consequences], and did not do so for other sales representatives in
6 Relator’s region. Under company policy, and in Relator’s experience, no other
7 sales rep was terminated without a performance improvement plan (“PIP”), unlike
8 the Relator.

9 251. In or about November 2013, Janssen made it clear to its sales representatives
10 that they were to begin to market Olysio for use off-label to treat HIV and renal
11 failure patients, and other uses that are not approved by the FDA. In November
12 2013, the FDA sent Janssen an approval letter for Olysio’s labeling. More
13 specifically, this FDA letter did not allow the Defendants to market Olysio for use
14 in HIV and renal failure patients. However, Janssen continued to market Olysio for
15 use in HIV and renal failure patients, as set forth above.

16 252. In or about November, 2013, Relator complained about Janssen’s off-label
17 marketing strategy to Relator’s manager. Relator also voiced concern about
18 Janssen’s use of kickbacks. For example, when District Manager Alan Williams
19 wrote about Dr. Sammy Saab getting paid for speaking on Olysio even though it
20 wasn’t his “go-to drug” and asked Regional Business Director (“RBD”) Mo Issa to
21 intervene on this issue. The RBD asked in turn for the representative to confront
22 the physician and ask “why with so many resources [speaker programs and
23 advisory board kickbacks] does Dr. Saab write such minimal number of patients on
24 Olysio?” The RBD proceeded to state that the Defendants would not be using
25 physicians that are not advocates of the products. And the RBD requested a
26 favorability matrix to be developed to measure ROI of retaining physicians as
27 speakers for products and their perceived value to the company. In this way, the

1 RBD was clearly requiring sales representatives to make certain that their speaker
2 arrangements with physicians were quid pro quo arrangements (See Exhibit 65).

3 253. Dr. Sammy Saab spoke at multiple dinners on Olysio during 2014-15.

4 Doctors arrived, signed-in, and got seated right away because they did not like to
5 come early. Dr. Saab would arrive early. As part of the scheme, the laptop and
6 projector were already set up by the restaurant staff, and Dr. Saab brought a flash
7 drive with his presentation slides. The average size of a dinner meeting was 12-22
8 people. Dr. Saab greeted the other doctors as they began to arrive. Dr. Saab nearly
9 always spoke to people that he worked with at the UCLA transplant program, and
10 he arranged with members of the audience prior to arriving at the dinner to ask
11 questions about the COSMOS study. Janssen personnel advised Dr. Saab in
12 advance of each dinner that he would not be able to talk off-label about using an
13 Olysio dual-therapy regimen like in the COSMOS study without a question from
14 the audience. Dr. Saab would arrange for a friend in the audience to ask him the
15 off-label question. Sometimes an attendee would forget to ask the off-label
16 question in the audience, so Dr. Saab would say, "did someone have a question
17 about the COSMOS study?", or the Janssen sales representative would step
18 forward and ask the off-label question, since that was the most important part of
19 the talk.

20 254. Again, in retaliation for these complaints, Relator was subjected to further
21 harassment and intimidation. Relator continued to be treated differently from other
22 sales representatives in the region. Relator had long been a graduate of the
23 management development program. Despite having elevated into the last stage of
24 the program, the management had asked Relator to repeat a series of classes that
25 were already completed. Despite the fact that Relator attempted to apply for
26 another position as the most qualified candidate, citing that Relator had ethical
27 issues selling the product, the management team intervened and reached the hiring
28

1 manager and told the hiring manager that Relator was job hopping. Relator had
2 been with the same company for nine (9) years at that point, and was not “job
3 hopping.” The same manager supported another member of the team that had none
4 of the qualifications to be successful in the new role.

5 255. For example, other sales representatives in Relator’s region were allowed to
6 take vacations or miss meetings in order to accommodate family obligations or to
7 run businesses on the side. Relator was pressured not to take vacation, and to keep
8 working over one hundred hours a week, while noted previously, running the
9 eleventh highest volume territory in the country while managing five other states.

10 Shortly after complaining about Janssen’s off-label promotions, Relator was
11 routinely required to attend promotional dinners with doctors, while colleagues in
12 the region were given the night off in order to plan activities with their families or
13 their own side businesses. In fact, the Regional Director himself had a side
14 business that he was spending time on while at the same time demanding a very
15 high amount of work hours from Relator. Relator was asked to work all the local
16 area drug expositions (over 14 additional days with no over time or respite).

17 Despite the intense emotional and social pressure, Relator worked nights for
18 dinners and for completing district management duties, and worked days for sales
19 calls and territory management. Relator was never compensated for these
20 additional hours despite CA regulations.

21 256. In addition, Relator was subjected to racial and religious discrimination by
22 Relator’s manager. For example, on June 26, 2014 while in a meeting in Denver,
23 Colorado, Relator’s manager Tyana Grant had her birthday celebrated at a meeting.
24 Ms. Grant had just come back from a church-related trip from Israel. Relator asked
25 her how her trip was, and Ms. Grant said Israel was beautiful, but the Palestinians
26 are like animals. Relator was shocked and asked her what she meant by that. Ms.
27 Grant said that the Muslim kids surrounded her bus and were begging for money.

1 Ms. Grant said that they weren't acting like humans, they were surrounding the bus
2 like animals, and shaking people down for money. Relator's own family's religious
3 background and ethnic heritage were viciously attacked in this manner, and as a
4 result Relator suffered extreme emotional and physical distress.

5 257. In April, 2015, Relator won a sales award for being the District
6 Representative of the Year, because Relator not only ran a sales territory
7 successfully, but Relator also ran an entire five state district and brought that
8 district to the number one position in sales. But even then, Relator was being
9 retaliated against by not being allowed by Defendant to be promoted to the next
10 level of employment as a permanent District Manager. Despite the success Relator
11 experienced in the field and in the district the RBD stated that Relator is not
12 flexible and does not appear to have a positive disposition and such a role would be
13 highly at risk.

14 258. On or about August 10, 2015, Defendants' employee Carrie Palmer from
15 Janssen's HR Office illegally disclosed the details of Relator's disability and
16 medical treatment to an outside party in violation of Relator's rights under HIPAA.

17 259. On August 11, 2015, an HR representative for Janssen terminated Relator by
18 mail, without paying Relator's accrued vacation time as per California law. Relator
19 was not given a severance package, as the other sales representatives who had been
20 laid off previously had been. There was no PIP (Performance Improvement Plan)
21 to warn Relator and ask for corrective action.

22 260. Janssen's stated reason for terminating Relator was for Relator's making of
23 additional ("side") income. However, most of the Defendants' sales representatives
24 and managers followed the same customary practice as Relator in creating a side
25 income. This conduct had occurred for many years in front of Defendant's
26 managers without any other sales reps receiving any criticism or complaints. For
27 example, the Regional Business Director Mo Issa was simultaneously the CEO of
28

1 another company, Noor Vitamins. This was information that was highly public and
2 understood as completely compliant as the RBD discussed going to Dubai for this
3 business and talked about his multiple business successes.

4 261. After the Relator reported the alleged fraud to Defendants' management, and
5 despite Relator's long history of employment and the fact that the Relator was an
6 exemplary employee, having won multiple sales awards nationally and regionally,
7 the Relator was discharged without notice. The discharge included Defendants'
8 employee Carrie Palmer from Defendants' human resources department contacting
9 an outside organization and illegally violating Relator's rights under Health
10 Insurance Portability and Accountability Act of 1996 ("HIPAA"). Here,
11 Defendants revealed the details of Relator's personal and private medical records,
12 and temporary disability, without Relator's knowledge and consent. Subsequently,
13 the Relator was discharged from that new employer without cause.

14 262. Furthermore, on or about August 10th, 2015, Defendants' human resources
15 department employee Carrie Palmer contacted Relators' new employer and
16 disclosed details of Relator's health issues to this new employer. Multiple
17 employees from the new employer including but not limited to employee A and
18 employee B informed the Relator of Defendant's egregious conduct. Relator was
19 subsequently terminated by the new employer on or about August 18th, 2015, only
20 days after the Defendants contacted.

21 263. Relator alleges other infractions including but not limited to
22 violating HIPPA and encroachment on Relator's privacy, COBRA violations, and
23 interference with the active medical treatment of an employee under distress and
24 during a period of active disability. Defendants retaliated against Relator by
25 terminating Relator's medical insurance, terminating Relator's disability insurance,
26 interfering with Relator's rights to continue insurance under Cobra, and by
27 refusing to pay for treatments for Relator's severe disabling condition which was

1 brought about by Defendants' hostile work environment described herein.
2 264. For example, despite medical evidence of Relator's inability to drive an
3 automobile, Defendants refused to make accommodation for the
4 Relator. Defendants' referring physician Dr. Orfus stated in Relator's Qualified
5 Medical Examiner ("QME") report that if Relator was unable to drive an
6 automobile, then Relator was unable to work. While Relator was qualified for
7 Long Term disability based on the QME and Relator's employee contract with
8 Defendants, and the long-term disability insurance that Relator personally paid for,
9 Defendants proceeded to rescind relator's disability claim. Relator contacted the
10 claims administrator Regina Carter for Prudential that is the long-term Disability
11 Plans administrator. Prudential's Regina Carter stated that Relator's claim was
12 being processed for payment and intact there was a case number
13 assigned. According to the claims administrator Regina Carter, the Defendants
14 interference with an application at this stage was extremely uncommon, and
15 Defendants requested Prudential to terminate the application in violation of state
16 law.

17 265. Defendants further blacklisted the Relator from gainful employment. Relator
18 is informed of verbal communications from August 2015 through June, 2016,
19 where several of the Defendants employees in human resources and executive
20 management, such as Regional Business Director Mo Issa, Helen Hutchins, Jason
21 Hammon, were overheard making false statements about the Relator. This includes
22 Defendants' sales representatives including Ron Lloyd and Julie Ewers, and several
23 managers, including Sunny Lee and Jennifer Brown. This conduct black-listed the
24 Relator and made Relator unemployable. And, to further undermine Relator's
25 credibility, Defendants' employees retaliated and maliciously accused the relator
26 of fraud. Defendants roguishly continued these malicious attacks through June
27 2016, almost one year after Relator's termination, and Defendants failed to curtail

1 these highly defamatory communications.

2 266. Another tactic that Defendants employed to further intimidate and harass the
3 Relator was the interference with Relator's disability application.

4 Consequently, Relator suffered a multitude of injuries such as physical and
5 debilitating illnesses and was still under treatment at the time of discharge.

6 267. Relator was a stellar, nationally-ranked sales representative of Defendants,
7 illustrated by Relator's record, multiple awards and written and verbal management
8 accolades. As a result of working over one hundred hours a week, verbal abuse
9 and a hostile work environment, Defendants terminated Relator under extreme
10 medical duress. At the time of termination, the Relator needed to see multiple
11 specialists to treat chronic refractory hemiplegic migraines, and Relator was placed
12 on a heavy daily prescription regimen to control excruciating pain, nausea and
13 disorientation. Relator was barely able to drive an automobile, keep food down,
14 and had to take multiple medications and see multiple specialists to for basic
15 activities such as walking and talking. Relator's health continued to decline and
16 deteriorate further caused by Defenadnts' hostile and illegal work environment
17 which was further aggravated by Defendants' retaliation, illegal termination,
18 violation of HIPPA, and defamation of Relator.

19 268. For example, prior to Relator's period of total disability, Relator's territory
20 produced nearly \$100 million in Olysio sales, yet relator was publicly reprimanded
21 for not producing more Simponi prescriptions and other prescription manufactured
22 and distributed by the Defendants. When Relator, an interim District Manager,
23 brought the Defendants' team performance to the number one sales position in the
24 United States of America, instead of encouragement, gratitude and positive
25 reinforcement, relator was told that the success was just a result of natural market
26 forces. When Relator contended several illegally business practices to the
27 Defendants, Relator was singled out as not being "positive" and not having "team

1 spirit” by the Defendants. Consequently, Relator was reprimanded both publicly
2 and privately, and was denied company benefits such as vacation and other
3 compensation.

4 269. Defendants continued to intimidate Relator by interfering with Relator’s
5 right to privacy, ability to receive adequate medical care, resolve disability, and
6 interfering with the Relator’s ability to maintain gainful employment and preserve
7 a 10-year career in pharmaceutical sales. The Defendants’ actions continued
8 unabated and given the fact that the Defendant has been under a Corporate

9 Integrity Agreement for two separate counts of fraud and off-label promotion,

10 270. As a direct and proximate result of Defendants’ unlawful actions as detailed
11 herein, Relator has suffered loss of employment opportunities, lost a potential
12 career, loss of dignity, suffered great humiliation, and emotional injuries
13 manifesting physical illness and severe emotional distress.

14 271. As a result of the conduct by Defendants of which Relator complains,
15 Plaintiff suffered and continues to suffer substantial losses in earnings and other
16 employee benefits. Relator will seek leave to amend this Complaint to state the
17 amount or will proceed according to proof at trial.

18 272. Relator suffered emotional distress as a result of the conduct by Defendants
19 of which Relator complains.

20 273. At all material times, Defendants, and each of them, knew that Relator
21 depended on Relator’s wages and other employee benefits as a source of earned
22 income. At all material times, Defendants were in a position of power over
23 Relator, with the potential to abuse that power.

24 274. Relator was in a vulnerable position because of Relator’s status as a
25 whistleblower, with a relative lack of power, because Relator had placed Relator’s
26 trust in Defendants, because Relator depended on Relator’s employment for
27 Relator’s self-esteem and sense of belonging, because Relator relied upon

1 Relator's employment as a source of income. Defendants were aware of Relator's
2 vulnerability and the reasons for it.

3 **DEFENDANTS' SCHEMES RESULTED IN FALSE CLAIMS TO**
4 **MEDICAID AND MEDICARE**

5 275. Defendants' business plans often included tracking of physicians by their
6 volume of Medicare and Medicaid patients, average duration of treatment, and the
7 average revenue from Defendants' drugs. Defendant management utilized this
8 Medicaid and Medicare volume information in order to determine which
9 physicians to target for expensive meals and cash payments and off-label sales
10 promotions.

11 276. Payments of consulting fees and expensive dinners and other incentives to
12 increase referrals to a physician for the use of Defendants' drugs is inappropriate
13 and illegal. According to the federal Health and Human Services Office of the
14 Inspector General (HHS OIG), paid meals would be inappropriate if they are tied
15 directly or indirectly to the generation of federal health care program business for
16 the manufacturer, or for the purposeful inducement of business. See, e.g., 68 F.R.
17 23738. ("these arrangements [entertainment, recreation, travel, meals, etc.]
18 potentially implicate the anti-kickback statute if any one purpose of the
19 arrangement is to generate business.")

20 277. Defendants' scheme to pay physicians and promote off-label sales resulted
21 in specific sales. Defendants, like most branded drug companies, monitor the
22 relationship of its sales to its promotional efforts over a very short timeframe;
23 Defendants would be concerned about a drop in sales within a certain therapeutic
24 regime not after a year look-back, or even a quarterly look-back, but over a period
25 of just weeks. Defendants' marketing and sales strategy documents show that at
26 least on a weekly basis Defendants were tracking prescription volume by
27 physician, and tracking the percentage change in prescribing habits of physicians

1 for Defendants drugs.

2 278. Additionally, Defendants tracked the return on investment (“ROI”) of paid
3 travel and expensive meals for physicians. Defendants’ sales representatives were
4 instructed to ask physicians for additional prescriptions when the physicians were
5 paid to speak at a lavish meal event, and told to track follow-up prescriptions by
6 the physician, and to hold the physicians accountable if the physicians did not
7 increase prescriptions of Defendants’ drugs. Physicians were made aware by
8 Defendants’ sales representatives that the physicians would not continue to be
9 invited to lavish meals if the physicians did not remain in the high volume
10 prescriber range, and if the physicians did not prescribe Defendants’ drugs.

11 Physicians who did not continue to prescribe Defendants’ drugs were tracked on a
12 quarterly basis by Defendants’ marketing and sales personnel, and were sometimes
13 penalized by being taken off target lists for invitations to future lavish meals and
14 offers of speaking engagements, paid research opportunities, and other perks.

15 279. Defendants pushed “prescribe to play,” quid pro quo-focused sales
16 strategies, which are based entirely on the amount of prescriptions written by the
17 physicians and the ability of the physician to influence other physicians to begin
18 prescribing Defendants’ drugs. The recipients of these awards and benefits were
19 selected by Defendants’ home office marketing department. Some ROI factors that
20 Defendants’ home office used to funnel kickbacks to physicians included but were
21 not limited to the physician recipients’ ability to prescribe Defendants’ drugs and
22 to influence other physicians to do so.

23 280. Defendants also instructed its sales representatives to review patient records
24 at physician’s offices and instruct them to switch their patients to receive
25 Defendants’ drugs instead of competitor drugs.

26 281. The evidence points to willful and premeditated schemes of off-label
27 promotion, kickbacks, and violations of patients’ HIPPA protections. The Relator,

1 who was vocal about these tactics, was retaliated against with unreasonable plans
2 of corrective action and ultimately wrongfully terminated.

3 **CONCLUSION**

4 282. Defendants' fraudulent activities, as set forth in this Complaint have resulted
5 in significant fraud on the government's health care systems. These concerted,
6 national schemes for fraudulent promotion of Defendants' drugs have resulted in
7 billions of dollars in unnecessary and fraudulent claims for reimbursement
8 increasing the cost of healthcare and wasting the American taxpayer dollar.

9 **COUNT I; FALSE CLAIMS ACT**

10 **CAUSING PRESENTATION OF FALSE OR FRAUDULENT CLAIMS**

11 283. This is a civil action by the Plaintiff, UNITED STATES, and the Relator,
12 ALEXANDER VOLKOFF, LLC, on behalf of the UNITED STATES and on
13 behalf of the Relator, against the Defendants: JANSSEN PHARMACEUTICA
14 PRODUCTS LP, JOHNSON & JOHNSON, and ORTHO-MCNEIL, under the
15 False Claims Act, 31 U.S.C. §§3729-32.

16 284. Relator realleges and incorporates the allegations above as if fully set for
17 herein and further alleges as follows:

18 285. The DEFENDANTS, from at least January 1, 2005 to the present date
19 knowingly [as defined in 31 USC, §3729(b)] caused to be presented to officers or
20 employees of the UNITED STATES GOVERNMENT and STATES
21 GOVERNMENTS false or fraudulent claims for payment or approval, in that the
22 DEFENDANTS, caused to be presented to officers or employees of the UNITED
23 STATES GOVERNMENT AND STATES GOVERNMENTS false or fraudulent
24 claims for the specified drugs (as the term "specified drugs" has been defined
25 throughout this Complaint) and caused the UNITED STATES and STATE
26 GOVERNMENTS to pay out sums of money to the healthcare providers and
27 suppliers of the DEFENDANTS' specified drugs, grossly in excess of the amounts

1 permitted by law, resulting in great financial loss to the UNITED STATES and
2 STATE GOVERNMENTS.

3 286. Because of the DEFENDANT PHARMACEUTICAL
4 MANUFACTURERS' conduct as set forth in this Count, the UNITED STATES
5 suffered actual damages in amount to be proven at trial, all in violation of 31
6 U.S.C. §3729(a)(1).

7 **COUNT II; FALSE CLAIMS ACT**

8 **CAUSING A FALSE RECORD OR STATEMENT TO BE MADE OR USED**
9 **TO GET A FALSE OR FRAUDULENT CLAIM PAID OR APPROVED BY**
10 **THE GOVERNMENT**

11 287. This is a civil action by the Plaintiff, UNITED STATES, and the Relator,
12 ALEXANDER VOLKOFF, LLC, on behalf of the UNITED STATES and on
13 behalf of the Relator, against the Defendants: JANSSEN PHARMACEUTICA
14 PRODUCTS LP, JOHNSON & JOHNSON, and ORTHO-MCNEIL, under the
15 False Claims Act, 31 U.S.C. §§3729-32.

16 288. Relator realleges and incorporates the allegations above as if fully set for
17 herein and further alleges as follows:

18 289. The DEFENDANTS, from At least January 1, 2005 to the present date
19 knowingly [as defined in 31 USC, §3729(b)] caused false records or statements to
20 be made or used to get false or fraudulent claims to be paid or approved by the
21 GOVERNMENT, in that the DEFENDANTS, caused false information about the
22 DEFENDANTS' drugs specified herein to be used by the GOVERNMENT to pay
23 or approve claims presented by healthcare providers and suppliers of the
24 DEFENDANTS' specified drugs, which claims were grossly in excess of the
25 amounts permitted by law, resulting in great financial loss to the UNITED
26 STATES and STATE GOVERNMENTS.

1 290. Because of the DEFENDANTS' conduct as set forth in this Count, the
 2 UNITED STATES suffered actual damages in excess of One Billion Dollars
 3 (\$1,000,000,000.00), all in violation of 31 U.S.C. §3729(a)(1).

4 **COUNT III; FALSE CLAIMS ACT**

5 **CAUSING FALSE RECORDS OR STATEMENT TO BE USED TO**
 6 **CONCEAL AN OBLIGATION TO PAY MONEY TO THE GOVERNMENT**

7 291. This is a civil action by the Plaintiff, UNITED STATES, and the Relator,
 8 ALEXANDER VOLKOFF, LLC, on behalf of the UNITED STATES and on
 9 behalf of the Relator, against the Defendants: JANSSEN PHARMACEUTICA
 10 PRODUCTS LP, JOHNSON & JOHNSON, and ORTHO-MCNEIL, under the
 11 False Claims Act, 31 U.S.C. §§3729-32.

12 292. Relator realleges and incorporates the allegations above as if fully set
 13 for herein and further alleges as follows:

14 293. The DEFENDANTS, from at least January 1, 2005 to the present date
 15 knowingly [as defined in 31 USC, §3729(b)] caused false records or statements to
 16 be made or used to conceal obligations to pay money to the GOVERNMENT, in
 17 that: the DEFENDANTS knowingly made, used or caused to be made or used false
 18 records or false statements, i.e., the false certifications made or caused to be made
 19 by Defendants material to an obligation to pay or transmit money to the
 20 Government or knowingly concealed or knowingly and improperly avoided or
 21 decreased an obligation to pay or transmit money or property to the Government.

22 294. Because of the DEFENDANTS' conduct as set forth in this Count, the
 23 UNITED STATES suffered actual damages in excess of One Billion Dollars
 24 (\$1,000,000,000.00), all in violation of 31 U.S.C. §3729(a)(1).

25 **COUNT IV; FALSE CLAIMS ACT**

26 **CAUSING PRESENTATION OF FALSE OR FRAUDULENT CLAIMS;**
 27 **ILLEGAL RENUMERATION**

1 295. This is a civil action by the Plaintiff, UNITED STATES, and the Relator,
2 ALEXANDER VOLKOFF, LLC, on behalf of the UNITED STATES and on
3 behalf of the Relator, against the Defendants: JANSSEN PHARMACEUTICA
4 PRODUCTS LP, JOHNSON & JOHNSON, and ORTHO-MCNEIL, under the
5 False Claims Act, 31 U.S.C. §§3729-32.

6 296. Relator realleges and incorporates the allegations above as if fully set for
7 herein and further alleges as follows:

8 297. The DEFENDANTS, from at least 2010 to the present date knew that the
9 prices charged to their customers for the specified drugs were significantly reduced
10 in the amount from the prices and costs represented by the DEFENDANTS and
11 upon which the DEFENDANTS knew the Medicaid claims would be approved and
12 paid. Accordingly, the DEFENDANTS have each knowingly offered or paid, or
13 caused to be offered or paid, directly or indirectly, overtly or covertly, in cash or in
14 kind, remuneration to their customers on the form of price reductions and/or in the
15 form of illegal remuneration from the States' Medicaid Programs to induce them to
16 purchase, order or arrange or to recommend purchasing, arranging or ordering the
17 specified drugs for which the DEFENDANTS knew that payment would be made,
18 in whole or in part, by the States' Medicaid Programs. Such financial inducement
19 is specifically prohibited by 42 U.S.C. §1320a-7b(b) and 18 U.S.C. §2

20 298. The DEFENDANTS' knowing and willful actions in arranging for their
21 customers to receive remuneration prohibited by 42 U.S.C. §1320a-7b(b), in
22 causing the omission of material information from the claims, and in causing the
23 failure to properly disclose and appropriately reflect the remuneration in the
24 claims, caused the claims for the specified drugs to be false and fraudulent claims
25 and caused the claims to be presented to the States' Medicaid Programs for
26 payment and approval in violation of 31 U.S.C. §3729(a)(1).

1 299. Because of the DEFENDANTS' conduct as set forth in this Count, the
2 UNITED STATES suffered actual damages in excess of One Billion Dollars
3 (\$1,000,000,000.00), all in violation of 31 U.S.C. §3729(a)(1).

4 **COUNT V; FALSE CLAIMS ACT**

5 **CAUSING A FALSE RECORD OR STATEMENT TO BE MADE OR USED**
6 **TO GET A FALSE OR FRAUDULENT CLAIM PAID OR APPROVED BY**
7 **THE GOVERNMENT; PROHIBITED REFERRALS, CLAIMS AND**
8 **COMPENSATION ARRANGEMENTS**

9 300. This is a civil action by the Plaintiff, UNITED STATES, and the Relator,
10 ALEXANDER VOLKOFF, LLC, on behalf of the UNITED STATES and on
11 behalf of the Relator, against the Defendants: JANSSEN PHARMACEUTICA
12 PRODUCTS LP, JOHNSON & JOHNSON, and ORTHO-MCNEIL, under the
13 False Claims Act, 31 U.S.C. §§3729-32.

14 301. Relator realleges and incorporates the allegations above as if fully set for
15 herein and further alleges as follows:

16 302. The DEFENDANTS, from at least 2010 to the present date knowingly
17 presented or caused to be presented, prohibited claims or bills to individuals and
18 other entities for designated health services [outpatient prescription drugs]
19 furnished pursuant to prohibited referrals from physicians, physician groups and/or
20 outpatient clinics with which the DEFENDANTS has financial relationships, for
21 which the DEFENDANTS knew that payment would be made, in whole or in part,
22 by the States' Medicaid Programs. Such prohibited referrals, claims bills and
23 compensation arrangements are specifically prohibited by 42 U.S.C.
24 §1395nn(a)(1)(B) and 18 U.S.C. §2.

25 303. The DEFENDANTS' knowingly made or used or caused referring
26 physicians, physician groups or outpatient clinics to make or use records or
27 statements to get false or fraudulent claims and bills for the DEFENDANTS'

1 outpatient prescription drugs to be paid or approved by the States' Medicaid
2 Programs.

3 304. The DEFENDANTS' knowing presentment or causing others to present,
4 claims or bills to the States' Medicaid programs in violation of 42 U.S.C.
5 §1395nn(a)(1)(B) without disclosing facts revealing said violations constituted the
6 making or using, or the causing others to make or use, false records or statements
7 to get a false or fraudulent claims paid or approved by the GOVERNMENT in
8 violation of 31 U.S.C. §3729(a)(2).

9 305. Because of the DEFENDANTS' conduct as set forth in this Count, the
10 UNITED STATES suffered actual damages in excess of One Billion Dollars
11 (\$1,000,000,000.00), all in violation of 31 U.S.C. §3729(a)(2).

12 **COUNT VI: FALSE CLAIMS ACT**

13 **CONSPIRING TO DEFRAUD THE GOVERNMENT BY GETTING A**
14 **FALSE OR FRAUDULENT CLAIM ALLOWED OR PAID**

15 306. This is a civil action by the Plaintiff, UNITED STATES, and the Relator,
16 ALEXANDER VOLKOFF, LLC, on behalf of the UNITED STATES and on
17 behalf of the Relator, against the Defendants: JANSSEN PHARMACEUTICA
18 PRODUCTS LP, JOHNSON & JOHNSON, and ORTHO-MCNEIL, under the
19 False Claims Act, 31 U.S.C. §§3729-32.

20 307. Relator realleges and incorporates the allegations above as if fully set for
21 herein and further alleges as follows:

22 308. With respect to State Medicaid Programs, this Count also applies to all
23 DEFENDANTS manufacturing specified drugs which: 1) were multiple-source
24 drugs and/or single-source drugs, 2) were subject to State Medicaid reimbursement
25 methodology similar to the Medicare "J Code" methodology, and 3) had a falsely
26 inflated reported AWP and/or WAC or another falsely inflated reported price or
27 cost if such price or cost was utilized in creating an array or prices or costs from
28

1 which one was selected or reimbursement of all versions of a given drug.

2 309. Each DEFENDANTS' liability as to this Count extends from the time it first
 3 reported a falsely inflated AWP and/or WAC, or in the case of Medicaid, a falsely
 4 inflated AWP and/or WAC or such other price cost used to create the array of drug
 5 prices or costs, until such time, if any, each DEFENDANT stopped reporting said
 6 inflated AWP and/or WAC or, in the case of Medicaid, stopped reporting said
 7 inflated AWP and/or WAC or such other reported price or cost used to create the
 8 array of drug prices or costs from which one was selected for reimbursement
 9 purposes.

10 310. Because of the DEFENDANTS' conduct as set forth in this Count, the
 11 UNITED STATES suffered actual damages in excess of One Billion Dollars
 12 (\$1,000,000,000.00), all in violation of 31 U.S.C. §3729(a)(3).

13 **COUNT VII**

14 **(Arkansas Medicaid Fraud False Claims Act, A.C.A. § 20-77-901 *et seq.*)**

15 311. Relator re-alleges and incorporates by reference each of the paragraphs
 16 above as if fully set forth herein and further alleges as follows.

17 312. Additionally, Relator states that the course of conduct described in this
 18 Complaint was a nationwide practice of Defendants. Defendants conduct business
 19 in the State of Arkansas. Upon information and belief, Defendants' actions
 20 described herein occurred in the State of Arkansas as well. This is a qui tam action
 21 brought by Relator and the State of Arkansas to recover treble damages and civil
 22 penalties under the Arkansas Medicaid Fraud False Claims Act, A.C.A. § 20-77-
 23 901 *et seq.*

24 313. The Arkansas Medicaid Fraud False Claims Act § 20-77-902 provides
 25 liability for any person who knowingly makes or causes to be made any false
 26 statement or representation of a material fact in any application for any benefit or
 27 payment under the Arkansas Medicaid program;

1 314. At any time knowingly makes or causes to be made any false statement or
2 representation of a material fact for use in determining rights to a benefit or
3 payment;

4 315. In addition, A.C.A. § 20-77-902(7)(A) prohibits soliciting, accepting, or
5 agreeing to accept any type of remuneration for recommending the purchase, lease,
6 or order of any good, facility, service, or item for which payment may be made
7 under the Arkansas Medicaid program.

8 316. Defendants violated the Arkansas Medicaid Fraud False Claims Act §20-77-
9 902(1) (2) & (7)(A) from at least 2001 to the present by engaging in the fraudulent
10 and illegal practices described herein.

11 317. Defendants furthermore violated the Arkansas Medicaid Fraud False Claims
12 Act § 20-77-902(1) & (2) and knowingly caused thousands of false claims to be
13 made, used and presented to the State of Arkansas from at least 2005 to the present
14 by its violation of federal and state laws, including A.C.A. § 20-77-902(7)(A), the
15 Anti-Kickback Act and Stark Act Requirements, as described herein.

16 318. The State of Arkansas, by and through the Arkansas Medicaid program and
17 other State health care programs, and unaware of Defendants' fraudulent and
18 illegal practices, paid the claims submitted by health care providers and third
19 payers in connection therewith.

20 319. Compliance with applicable Medicare, Medicaid and the various other
21 federal and state laws cited herein was an implied, and upon information and
22 belief, also an express condition of payment of claims submitted to the State of
23 Arkansas in connection with Defendants' fraudulent and illegal practices.

24 320. Had the State of Arkansas known that Defendants was violating the federal
25 and state laws cited herein, it would not have paid the claims submitted by health
26 care providers and third party payers in connection with Defendants' fraudulent
27 and illegal practices.

1 321. As a result of Defendants' violations of § 20-77-902(1) (2) & (7)(A), the
2 State of Arkansas has been damaged in an amount far in excess of millions of
3 dollars exclusive of interest.

4 322. Relator is a private person with direct and independent knowledge of the
5 allegations of this Complaint, and brought this action pursuant to A.C.A. § 20-77-
6 911(a) on behalf of themselves and the State of Arkansas.

7 323. This Court is requested to accept supplemental jurisdiction of this related
8 state claim as it is predicated upon the exact same facts as the federal claim, and
9 merely asserts separate damage to the State of Arkansas in the operation of its
10 Medicaid program.

11 324. Pursuant to the Arkansas Medicaid Fraud False Claims Act, the State of
12 Arkansas and Relator are entitled to the following damages as against Defendants:

13 325. To the STATE OF ARKANSAS:

14 326. Three times the amount of actual damages which the State of Arkansas has
15 sustained as a result of Defendants' fraudulent and illegal practices;

16 327. A civil penalty of not less than \$5,000 and not more than \$10,000 for each
17 false claim which Defendants caused to be presented to the State of Arkansas;

18 328. Prejudgment interest; and

19 329. All costs incurred in bringing this action.

20 330. To RELATOR:

21 331. The maximum amount allowed pursuant to A.C.A. § 20-77-911(a) and /or
22 any other applicable provision of law;

23 332. Reimbursement for reasonable expenses which Relator incurred in
24 connection with this action;

25 333. An award of reasonable attorneys' fees and costs; and

26 334. Such further relief as this court deems equitable and just.

27 ///

COUNT VIII**(California False Claims Act, Cal. Gov't Code § 12650 *et seq.*)**

335. Relator re-allege and incorporate the allegations above as if fully set for herein and further alleges as follows.

336. Additionally, Relator state that the course of conduct described in this Complaint was a nationwide practice of Defendants. Defendants conduct business in the State of California. Upon information and belief, Defendants' actions described herein occurred in the State of California as well.

337. This is a qui tam action brought by Relator and the State of California to recover treble damages and civil penalties under the California False Claims Act, Cal. Gov't. Code § 12650 *et seq.*

338. Cal. Gov't Code § 12651(a) provides liability for any person who—

339. Knowingly presents, or causes to be presented, to an officer or employee of the state or any political division thereof, a false claim for payment or approval;

340. Knowingly makes, uses, or causes to be made or used a false record of statement to get a false claim paid or approved by the state or by any political subdivision;

341. Conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision.

342. Is a beneficiary of an inadvertent submission of a false claim to the state or a political subdivision, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

343. In addition, the payment or receipt of bribes or kickbacks is prohibited under Cal. Bus. & Prof. Code §§ 650 and 650.1, and is also specifically prohibited in treatment of Medi-Cal patients pursuant to Cal. Welf. & Inst. Code § 14107.2.

344. Defendants violated Cal Bus. & Prof. Code §§ 650 and 650.1 and Cal. Welf.

1 & Inst. Code § 14107.2 from at least 2005 to the present by engaging in the
2 fraudulent and illegal practices described herein.

3 345. Defendants furthermore violated Cal. Gov't Code § 12651(a) and knowingly
4 caused hundreds of thousands of false claims to be made, used and presented to the
5 State of California from at least 2005 to the present by its violation of federal and
6 state laws, including Cal. Bus. & Prof. Code §§ 650 and 650.1 and Cal. Welf. &
7 Inst. Code § 14107.2, the Anti-Kickback Act and Stark Act Requirements, as
8 described herein.

9 346. The State of California, by and through the California Medicaid program
10 and other state health care programs, and unaware of Defendants' fraudulent and
11 illegal practices, paid the claims submitted by health care providers and third party
12 payers in connection therewith.

13 347. Compliance with applicable Medicare, Medi-Cal and the various other
14 federal and state laws cited herein was implied, and upon information and belief,
15 also an express condition of payment of claims submitted to the State of California
16 in connection with Defendants' fraudulent and illegal practices.

17 348. Had the State of California known that Defendants were violating the federal
18 and state laws cited herein, it would not have paid the claims submitted by health
19 care providers and third party payers in connection with Defendants' fraudulent
20 and illegal practices.

21 349. As a result of Defendants' violations of Cal. Gov't Code § 12651(a), the
22 State of California has been damaged in an amount far in excess of millions of
23 dollars exclusive of interest.

24 350. Relator are private persons with direct and independent knowledge of the
25 allegations of this Complaint, who have brought this action pursuant to Cal. Gov't
26 Code § 12652(c) on behalf of themselves and the State of California.

27 351. This Court is requested to accept supplemental jurisdiction over this related

1 state claim as it is predicated upon the same exact facts as the federal claim, and
2 merely asserts separate damages to the State of California in the operation of its
3 Medicaid program.

4 352. Pursuant to the California False Claims Act, the State of California and
5 Relator are entitled to the following damages as against Defendants:

6 353. To the STATE OF CALIFORNIA:

7 354. Three times the amount of actual damages which the State of California has
8 sustained as a result of Defendants' fraudulent and illegal practices;

9 355. A civil penalty of not less than \$5,500 and not more than \$11,000 for each
10 false claim which Defendants presented or caused to be presented to the State of
11 California;

12 356. Prejudgment interest; and

13 357. All costs incurred in bringing this action.

14 358. To RELATOR:

15 359. The maximum amount allowed pursuant to Cal. Gov't Code § 12652 and /or
16 any other applicable provision of law;

17 360. Reimbursement for reasonable expenses which Relator incurred in
18 connection with this action;

19 361. An award of reasonable attorneys' fees and costs; and

20 362. Such further relief as this Court deems equitable and just.

21 **COUNT IX**

22 **(California Insurance Frauds Prevention Act, Cal. Ins. Code § 1871.7 *et seq.*)**

23 363. Relator re-allege and incorporate the allegations above as if fully set for
24 herein and further alleges as follows.

25 364. This is a claim for treble damages and penalties under the California
26 Insurance Fraud Prevention Act.

27 365. By virtue of the acts described above, Defendants knowingly utilized a

1 scheme by which they improperly procured "runners, cappers, steerers, and other
2 persons" to procure patients who held private insurance contracts and against
3 whom Defendants could cause the filing of claims for payment. *See* Cal. Ins. Code
4 § 1871.7(a).

5 366. Defendants knowingly presented, or caused to be presented, false or
6 fraudulent claims to the private insurers in California, or for patients in California
7 those insurers covered, for payment or approval in violation of each patient's
8 private health insurance contract.

9 367. By virtue of the acts described above, Defendants knowingly made, used, or
10 caused to be made or used false records and statements and omitted material facts
11 to induce the private insurers in California, or for patients in California covered by
12 those insurers, to approve or pay such false and fraudulent claims.

13 368. By virtue of the acts described above, the Defendants conspired to violate
14 the California Insurance Fraud Prevention Act and each patient's private health
15 insurance contract.

16 369. The private insurers in California, or those insurers that covered patients in
17 California, unaware of the falsity of the records, statements, and claims made,
18 used, presented, or caused to be presented by Defendants, paid and continue to pay
19 the claims that are non-payable as a result of Defendants' illegal conduct.

20 370. Defendants knowingly submitted and/or caused to be made or used false
21 records or false statements in order to avoid or decrease their respective obligations
22 to return overpayments to these private insurance companies.

23 371. By reason of Defendants' acts, these private insurance companies have been
24 damaged, and continue to be damaged, in a substantial amount to be determined at
25 trial.

26 372. Each claim for reimbursement that was a result of the Defendants' scheme
27 represents a false or fraudulent record or statement and a false or fraudulent claim

1 for payment.

2 373. The State of California is entitled to the maximum penalty of \$10,000.00 for
3 each and every false or fraudulent claim, record, or statement made, used,
4 presented, or caused to be made, used, or presented by Defendants.

5 374. WHEREFORE, Relators request the following relief:

6 375. That this Court enter judgment against Defendants in an amount equal to
7 three times the amount of damages that the private insurance companies have
8 sustained because of Defendants' actions, plus a civil penalty of not less than
9 \$5,000.00 and not more than \$10,000.00 for each violation of Cal. Ins. Code §
10 1871.7(a) and (b);

11 376. At least thirty percent (30%) and up to forty percent (40%) of the proceeds
12 of this action to the Relators if the State of California elects to intervene, and forty
13 percent (40%) to fifty percent (50%) if it does not;

14 377. Relators' attorneys' fees, litigation and investigation costs, and other related
15 expenses; and

16 378. Such other relief as the Court deems just and appropriate.

17 **COUNT X**

18 **(Colorado Medicaid False Claims Act, Col. Rev. Stat. §§ 25.5-4-303.5 *et seq.*)**

19 379. Relator re-allege and incorporate the allegations above as if fully set for
20 herein and further alleges as follows.

21 380. Additionally, Relator state that the course of conduct described in this
22 Complaint was a nationwide practice of Defendants. Defendants conduct business
23 in the State of Colorado. Upon information and belief, Defendants' actions
24 described herein occurred in the State of Colorado as well.

25 381. This is a qui tam action brought by Relator and the State of Colorado to
26 recover treble damages and civil penalties under the Colorado Medicaid False
27 Claims Act, Colorado Revised Statutes § 25.5-4-303.5. *et seq.*

1 382. Colorado Revised Statutes § 25.5-4-305 provides liability for any person
2 who-

3 383. Knowingly presents, or causes to be presented, to an officer or employee of
4 the state a false or fraudulent claim for payment or approval;

5 384. Knowingly makes, uses, or causes to be made or used a false record or
6 statement material to a false or fraudulent claim;

7 385. Has possession, custody, or control of property or money used, or to be used,
8 by the state in connection with the "Colorado Medical Assistance Act" and
9 knowingly delivers, or causes to be delivered, less than all of the money or
10 property;

11 386. Authorizes the making or delivery of a document certifying receipt of
12 property used, or to be used, by the state in connection with the "Colorado Medical
13 Assistance Act" and, intending to defraud the state, makes or delivers the receipt
14 without completely knowing that the information on the receipt is true;

15 387. Knowingly buys, or receives as a pledge of an obligation or debt, public
16 property from an officer or employee of the state in connection with the "Colorado
17 Medical Assistance Act" who lawfully may not sell or pledge the property;

18 388. Knowingly makes, uses, or causes to be made or used, a false record or
19 statement material to an obligation to pay or transmit money or property to the
20 state in connection with the "Colorado Medical Assistance Act", or knowingly
21 conceals or knowingly and improperly avoids or decreases an obligation to pay or
22 transmit money or property to the state in connection with the "Colorado Medical
23 Assistance Act;"

24 389. Conspires to commit a violation of paragraphs (a) to (f) of this subsection.

25 390. Defendants violated Colorado Revised Statutes § 25.5-4-305 from at least
26 2005 to the present by engaging in the fraudulent and illegal practices described
27 herein.

1 391. Defendants furthermore violated Colorado Revised Statutes § 25.5-4-305
2 and knowingly caused thousands of false claims to be made, used and presented to
3 the State of Colorado from at least 2005 to the present by its violation of federal
4 and state laws, including the Anti-Kickback Act, and the Stark Act, as described
5 herein.

6 392. The State of Colorado, by and through the State of Colorado Medicaid
7 program and other state health care programs, and unaware of Defendants'
8 fraudulent and illegal practices, paid the claims submitted by health care providers
9 and third payers in connection therewith.

10 393. Compliance with applicable Medicare, Medicaid and the various other
11 federal and state laws cited herein was an implied, and upon information and
12 belief, also an express condition of payment of claims submitted to the State of
13 Colorado in connection with Defendants' fraudulent and illegal practices.

14 394. Had the State of Colorado known that Defendants were violating the federal
15 and state laws cited herein, it would not have paid the claims submitted by health
16 care providers and third party payers in connection with Defendants' fraudulent
17 and illegal practices.

18 395. As a result of Defendants' violations of Colorado Revised Statutes § 25.5-4-
19 305 the State of Colorado has been damaged in an amount far in excess of millions
20 of dollars exclusive of interest.

21 396. Relator have direct and independent knowledge of the allegations of this
22 Complaint, who have brought this action pursuant to Colorado Revised Statutes §
23 25.5-4-306(2) on behalf of itself and the State of Colorado.

24 397. This Court is requested to accept supplemental jurisdiction of this related
25 state claim as it is predicated upon the exact same facts as the federal claim, and
26 merely asserts separate damage to the State of Colorado in the operation of its
27 Medicaid program.

1 398. Pursuant to the Colorado Medicaid False Claims Act, the State of Colorado
 2 and Relator are entitled to the following damages as against Defendants:

3 399. To the STATE OF COLORADO:

4 400. Three times the amount of actual damages which the State of Colorado has
 5 sustained as a result of Defendants' fraudulent and illegal practices;

6 401. A civil penalty of not less than \$5,500 and not more than \$11,000 for each
 7 false claim which Defendants caused to be presented to the State of Colorado;

8 402. Prejudgment interest; and

9 403. All costs incurred in bringing this action.

10 404. To RELATOR:

11 405. The maximum amount allowed pursuant to Colorado Revised Statutes §
 12 25.5-4-306(4) and /or any other applicable provision of law;

13 406. Reimbursement for reasonable expenses which Relator incurred in
 14 connection with this action;

15 407. An award of reasonable attorneys' fees and costs; and

16 408. Such further relief as this court deems equitable and just.

17 **COUNT XI**

18 **(Connecticut False Claims Act for Medical Assistance Programs, Connecticut**

19 **General Statutes § 17b-301b. *et seq.*)**

20 409. Relator re-allege and incorporate the allegations above as if fully set for
 21 herein and further alleges as follows.

22 410. Additionally, Relator state that the course of conduct described in this
 23 Complaint was a nationwide practice of Defendants. Defendants conduct business
 24 in the State of Connecticut. Upon information and belief, Defendants' actions
 25 described herein occurred in the State of Connecticut as well.

26 411. This is a qui tam action brought by Relator and the State of Connecticut to
 27 recover treble damages and civil penalties under the Connecticut False Claims Act

1 for Medical Assistance Programs, Connecticut General Statutes § 17b-301b. *et seq.*

2 412. Connecticut General Statutes § 17b-301b. provides liability for any person
3 who-

4 413. Knowingly presents or causes to be presented to an officer or employee of
5 the state a false or fraudulent claim for payment or approval under a medical
6 assistance program administered by the Department of Social Services;

7 414. Knowingly make, use or cause to be made or used, a false record or
8 statement to secure the payment or approval by the state of a false or fraudulent
9 claim under a medical assistance program administered by the Department of
10 Social Services;

11 415. Conspire to defraud the state by securing the allowance or payment of a false
12 or fraudulent claim under a medical assistance program administered by the
13 Department of Social Services.

14 416. Defendants violated Connecticut General Statutes § 17b-301b from at least
15 2005 to the present by engaging in the fraudulent and illegal practices described
16 herein.

17 417. Defendants furthermore violated Connecticut General Statutes § 17b-301b
18 and knowingly caused thousands of false claims to be made, used and presented to
19 the State of Connecticut from at least 2005 to the present by its violation of federal
20 and state laws, including the Anti-Kickback Act, and the Stark Act, as described
21 herein.

22 418. The State of Connecticut, by and through the State of Connecticut Medicaid
23 program and other state health care programs, and unaware of Defendants'
24 fraudulent and illegal practices, paid the claims submitted by health care providers
25 and third payers in connection therewith.

26 419. Compliance with applicable Medicare, Medicaid and the various other
27 federal and state laws cited herein was an implied, and upon information and

1 belief, also an express condition of payment of claims submitted to the State of
2 Connecticut in connection with Defendants' fraudulent and illegal practices.

3 420. Had the State of Connecticut known that Defendants were violating the
4 federal and state laws cited herein, it would not have paid the claims submitted by
5 health care providers and third party payers in connection with Defendants'
6 fraudulent and illegal practices.

7 421. As a result of Defendants' violations of Connecticut General Statutes § 17b-
8 301b the State of Connecticut has been damaged in an amount far in excess of
9 millions of dollars exclusive of interest.

10 422. Relator have direct and independent knowledge of the allegations of this
11 Complaint, who have brought this action pursuant to Connecticut General Statutes
12 § 17b-301d on behalf of itself and the State of Connecticut.

13 423. This Court is requested to accept supplemental jurisdiction of this related
14 state claim as it is predicated upon the exact same facts as the federal claim, and
15 merely asserts separate damage to the State of Connecticut in the operation of its
16 Medicaid program.

17 424. Pursuant to the Connecticut False Claims Act for Medical Assistance
18 Programs, the State of Connecticut and Relator are entitled to the following
19 damages as against Defendants:

20 425. To the STATE OF CONNECTICUT:

21 426. Three times the amount of actual damages which the State of Connecticut
22 has sustained as a result of Defendants' fraudulent and illegal practices;

23 427. A civil penalty of not less than \$5,500 and not more than \$11,000 for each
24 false claim which Defendants caused to be presented to the State of Connecticut;

25 428. Prejudgment interest; and

26 429. All costs incurred in bringing this action.

27 430. To RELATOR:

1 431. The maximum amount allowed pursuant to Connecticut General Statutes §
2 17b-301 and /or any other applicable provision of law;

3 432. Reimbursement for reasonable expenses which Relator incurred in
4 connection with this action;

5 433. An award of reasonable attorneys' fees and costs; and

6 434. Such further relief as this court deems equitable and just.

7 **COUNT XII**

8 **(Delaware Medicaid False Claims Act, 6 Del. C. § 1201 *et seq.*)**

9 435. Relator re-allege and incorporate the allegations above as if fully set for
10 herein and further alleges as follows.

11 436. Additionally, Relator state that the course of conduct described in this
12 Complaint was a nationwide practice of Defendants. Defendants conduct business
13 in the State of Delaware. Upon information and belief, Defendants' actions
14 described herein occurred in Delaware as well.

15 437. This is a qui tam action brought by Relator and the State of Delaware to
16 recover treble damages and civil penalties under the Delaware Medicaid False
17 Claims Act, 6 Del. C. § 1201 *et seq.*

18 438. 6 Del. C. § 1201 *et seq.* provides liability for any person who—

19 439. Knowingly presents, or causes to be presented, directly or indirectly, to an
20 officer or employee of the Government a false or fraudulent claim for payment or
21 approval;

22 440. Knowingly makes, uses or causes to be made or used, directly or indirectly,
23 a false record or statement to get a false or fraudulent claim paid or approved;

24 441. Conspires to defraud the Government by getting a false or fraudulent claim
25 allowed or paid;

26 442. Knowingly makes, uses, or causes to be made or used a false record or
27 statement to conceal, avoid, increase or decrease an obligation to pay or transmit

1 money or property to or from the Government.

2 443. Further, 31 Del. C. § 1005 provides that— It shall be unlawful for any
3 person to offer or pay any remuneration (including any kickback, bribe or rebate)
4 directly or indirectly, in cash or in kind to induce any other person . . . [t]o
5 purchase, lease, order or arrange for or recommend purchasing, leasing or ordering
6 any property, facility, service, or item of medical care or medical assistance for
7 which payment may be made in whole or in part under any public assistance
8 program.

9 444. Defendants violated 6 Del. C. § 1201 and knowingly caused hundreds of
10 thousands of false claims to be made, used and presented to the State of Delaware
11 from 2005 to the present by its violation of federal and state laws, including 31
12 Del. C. §1005, and Anti-Kickback Act and the Stark Act Requirements, as
13 described herein.

14 445. The State of Delaware, by and through the Delaware Medicaid program and
15 other state health care programs, and unaware of Defendants' fraudulent and illegal
16 practices, paid the claims submitted by health care providers and third party payers
17 in connection therewith.

18 446. Compliance with applicable Medicare, Medicaid and the various other
19 federal and state laws cited herein was an implied, and upon information and
20 belief, also an express condition of payment of claims submitted to the State of
21 Delaware in connection with Defendants' fraudulent and illegal practices.

22 447. Had the State of Delaware known that Defendants were violating the federal
23 and state laws cited herein, it would not have paid the claims submitted by health
24 care providers and third party payers in connection with Defendants' fraudulent
25 and illegal practices.

26 448. As a result of Defendants' violations of 6 Del C. § 1201(a), the State of
27 Delaware has been damage in an amount far in excess of millions of dollars

1 exclusive of interest.

2 449. Defendants did not, within 30 days after it first obtained information as to
3 such violations, furnish such information to officials of the State responsible for
4 investigating false claims violations, did not otherwise fully cooperate with any
5 investigation of the violations, and have not otherwise furnished information to the
6 State regarding the claims for reimbursement at issue.

7 450. Relator are private persons with direct and independent knowledge of the
8 allegations of this Complaint, who have brought this action pursuant to 6 Del. C. §
9 1203(b) on behalf of themselves and the State of Delaware.

10 451. This Court is requested to accept supplemental jurisdiction of this related
11 state claim as it is predicated upon the exact same facts as the federal claim, and
12 merely asserts separate damage to the State of Delaware in the operation of its
13 Medicaid program.

14 452. Pursuant to the Delaware Medicaid False Claims Act, the State of Delaware
15 and Relator are entitled to the following damages as against Defendants:

16 453. To the STATE OF DELAWARE:

17 454. Three times the amount of actual damages which the State of Delaware has
18 sustained as a result of Defendants' fraudulent and illegal practices;

19 455. A civil penalty on not less than \$5,500 and not more than \$ 11,000 for each
20 false claim which Defendants caused to be presented to the State of Delaware;

21 456. Prejudgment interest; and

22 457. All costs incurred in bringing this action.

23 458. To RELATOR:

24 459. The maximum amount allowed pursuant to 6 Del C. § 1205, and /or any
25 other applicable provision of law;

26 460. Reimbursement for reasonable expenses which Relator incurred in
27 connection with this action; and

1 461. An award of reasonable attorneys' fees and costs; and

2 462. Such further relief as this court deems equitable and just.

3 **COUNT XIII**

4 **(District of Columbia Procurement Reform Amendment Act, D.C. § 2-308.13**

5 ***et seq.*)**

6 463. Relator re-allege and incorporate the allegations above as if fully set for
7 herein and further alleges as follows.

8 464. Additionally, Relator state that the course of conduct described in this
9 Complaint was a nationwide practice of Defendants. Defendants conduct business
10 in the District of Columbia. Upon information and belief, Defendants' actions
11 described herein occurred in the District of Columbia as well.

12 465. This is a qui tam action brought by Relator and the District of Columbia to
13 recover treble damages and civil penalties under the District of Columbia
14 Procurement Reform Amendment Act, D.C. § 2-308.13 *et seq.*

15 466. D.C. Code § 2-30814(a) provides liability for any person who-

16 467. Knowingly presents, or causes to be presented, to an officer or employee of
17 the District a false claim for payment or approval;

18 468. Knowingly makes, uses or causes to be made or used, a false record or
19 statement to get a false claim paid or approved by the District;

20 469. Conspires to defraud the District by getting a false claim allowed or paid by
21 the District;

22 470. Is the beneficiary of an inadvertent submission of a false claim to the
23 District, subsequently discovers the falsity of the claim, and fails to disclose the
24 false claim to the District.

25 471. In addition, D.C. Code § 4-802(c) prohibits soliciting, accepting, or agreeing
26 to accept any type of remuneration for the following:

27 472. Referring a recipient to a particular provider of any item or service or for

1 which payment may be made under the District of Columbia Medicaid program; or
2 473. Recommending the purchase, lease, or order of any good, facility, service, or
3 item for which payment may be made under the District of Columbia Medicaid
4 Program.

5 474. Defendants violated D. C. Code § 4-802(c) from at least 2005 to the present
6 by engaging in the fraudulent and illegal practices described herein.

7 475. Defendants furthermore violated D. C. Code § 2-308.14(a) and knowingly
8 caused thousands of false claims to be made, used and presented to the District of
9 Columbia from at least 2005 to the present by its violation of federal and state
10 laws, including D. C. Code § 4-802(c), the Anti-Kickback Act and the Stark Act,
11 as described herein.

12 476. The District of Columbia, by and through the District of Columbia Medicaid
13 program and other state health care programs, and unaware of Defendants'
14 fraudulent and illegal practices, paid the claims submitted by health care providers
15 and third party payers in connection therewith.

16 477. Compliance with applicable Medicare, Medicaid and the various other
17 federal and state laws cited herein was an implied, and upon information and
18 belief, also an express condition of payment of claims submitted to the District of
19 Columbia in connection with Defendants' fraudulent and illegal practices.

20 478. Had the District of Columbia known that Defendants were violating the
21 federal and state laws cited herein, it would not have paid the claims submitted by
22 health care providers and third party payers in connection with Defendants'
23 fraudulent and illegal practices.

24 479. As a result of Defendants' violations of D.C. Code § 2-308.14(a) the District
25 of Columbia has been damaged in an amount far in excess of millions of dollars
26 exclusive of interest.

27 480. Relator are private persons with direct and independent knowledge of the

1 allegations of this Complaint, who have brought this action pursuant to D.C. Code
2 § 2-308.15(b) on behalf of himself and the District of Columbia.

3 481. This Court is requested to accept supplemental jurisdiction of this related
4 state claim as it is predicated upon the exact same facts as the federal claim, and
5 merely asserts separate damage to the District of Columbia in the operation of its
6 Medicaid program.

7 482. Pursuant to the District of Columbia Procurement Reform Amendment Act,
8 the District of Columbia and Relator are entitled to the following damages as
9 against Defendants:

10 483. To the DISTRICT OF COLUMBIA:

11 484. Three times the amount of actual damages which the District of Columbia
12 has sustained as a result of Defendants' fraudulent and illegal practices;

13 485. A civil penalty of not less than \$5,500 and not more than \$11,000 for each
14 false claim which Defendants caused to be presented to the District of Columbia;

15 486. Prejudgment interest; and

16 487. All costs incurred in bringing this action.

17 488. To RELATOR:

18 489. The maximum amount allowed pursuant to D. C. Code § 2-308.15(f) and /or
19 any other applicable provision of law;

20 490. Reimbursement for reasonable expenses which Relator incurred in
21 connection with this action;

22 491. An award of reasonable attorneys' fees and costs; and

23 492. Such further relief as this court deems equitable and just.

24 **COUNT XIV**

25 **(Florida False Claims Act, Fla. Stat. §§ 68.081 *et seq.*)**

26 493. Relator re-allege and incorporate the allegations above as if fully set for
27 herein and further alleges as follows.

1 494. Additionally, Relator state that the course of conduct described in this
2 Complaint was a nationwide practice of Defendants. Defendants conduct business
3 in the State of Florida. Upon information and belief, Defendants' actions described
4 herein occurred in the State of Florida as well.

5 495. This is a qui tam action brought by Relator and the State of Florida to
6 recover treble damages and civil penalties under the Florida False Claims Act,
7 West's F.S.A. § 68.081 *et seq.*

8 496. West's F.S.A. § 68.082 provides liability for any person who-

9 497. Knowingly presents or causes to be presented to an officer or employee of
10 an agency a false claim for payment or approval

11 498. Knowingly makes, uses, or causes to be made or used a false record or
12 statement to get a false or fraudulent claim paid or approved by an agency

13 499. Conspires to submit a false claim to an agency or to deceive an agency for
14 the purpose of getting a false or fraudulent claim allowed or paid

15 500. Defendants violated West's F.S.A. § 68.082 from at least 2005 to the present
16 by engaging in the fraudulent and illegal practices described herein.

17 501. Defendants furthermore violated West's F.S.A. § 68.082 and knowingly
18 caused thousands of false claims to be made, used and presented to the State of
19 Florida from at least 2005 to the present by its violation of federal and state laws,
20 including the Anti-Kickback Act, and the Stark Act, as described herein.

21 502. The State of Florida, by and through the State of Florida Medicaid program
22 and other state health care programs, and unaware of Defendants' fraudulent and
23 illegal practices, paid the claims submitted by health care providers and third
24 payers in connection therewith.

25 503. Compliance with applicable Medicare, Medicaid and the various other
26 federal and state laws cited herein was an implied, and upon information and
27 belief, also an express condition of payment of claims submitted to the State of

1 Florida in connection with Defendants' fraudulent and illegal practices.

2 504. Had the State of Florida known that Defendants were violating the federal
3 and state laws cited herein, it would not have paid the claims submitted by health
4 care providers and third party payers in connection with Defendants' fraudulent
5 and illegal practices.

6 505. As a result of Defendants' violations of West's F.S.A. § 68.082 the State of
7 Florida has been damaged in an amount far in excess of millions of dollars
8 exclusive of interest.

9 506. Relator are private persons with direct and independent knowledge of the
10 allegations of this Complaint, who have brought this action pursuant to West's
11 F.S.A. § 68.083(2) on behalf of themselves and the State of Florida.

12 507. This Court is requested to accept supplemental jurisdiction of this related
13 state claim as it is predicated upon the exact same facts as the federal claim, and
14 merely asserts separate damage to the State of Florida in the operation of its
15 Medicaid program.

16 508. Pursuant to the Florida False Claims Act, the State of Florida and Relator are
17 entitled to the following damages as against Defendants:

18 509. To the STATE OF FLORIDA:

19 510. Three times the amount of actual damages which the State of Florida has
20 sustained as a result of Defendants' fraudulent and illegal practices;

21 511. A civil penalty of not less than \$5,500 and not more than \$11,000 for each
22 false claim which Defendants caused to be presented to the State of Florida;

23 512. Prejudgment interest; and

24 513. All costs incurred in bringing this action.

25 514. To RELATOR:

26 515. The maximum amount allowed pursuant to West's F.S.A. § 68.085 and /or
27 any other applicable provision of law;

1 516. Reimbursement for reasonable expenses which Relator incurred in
 2 connection with this action;

3 517. An award of reasonable attorneys' fees and costs; and

4 518. Such further relief as this court deems equitable and just.

5 **COUNT XV**

6 **(Georgia State False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 *et seq.*)**

7 519. Relator re-allege and incorporate the allegations above as if fully set for
 8 herein and further alleges as follows.

9 520. Additionally, Relator state that the course of conduct described in this
 10 Complaint was a nationwide practice of Defendants. Defendants conduct business
 11 in the State of Georgia. Upon information and belief, Defendants' actions
 12 described herein occurred in Georgia as well.

13 521. This is a qui tam action brought by Relator and the State of Georgia to
 14 recover treble damages and civil penalties under the Georgia State False Medicaid
 15 Claims Act, Ga. Code Ann. § 49-4-168 *et seq.*

16 522. Ga. Code Ann. § 49-4-168.1 *et seq.* provides liability for any person who—

17 523. Knowingly presents or causes to be presented to the Georgia Medicaid
 18 program a false or fraudulent claim for payment or approval;

19 524. Knowingly makes, uses, or causes to be made or used, a false record or
 20 statement to get a false or fraudulent claim paid or approved by the Georgia
 21 Medicaid program;

22 525. Conspires to defraud the Georgia Medicaid program by getting a false or
 23 fraudulent claim allowed or paid;

24 526. Knowingly makes, uses, or causes to be made or used, a false record or
 25 statement to conceal, avoid, or decrease an obligation to pay, repay or transmit
 26 money or property to the State of Georgia.

27 527. Defendants violated Ga. Code Ann. § 49-4-168.1 and knowingly caused

1 hundreds of thousands of false claims to be made, used and presented to the State
2 of Georgia from 2005 to the present by its violation of federal and state laws,
3 including the Anti-Kickback Act and the Stark Act, as described herein.

4 528. The State of Georgia, by and through the Georgia Medicaid program and
5 other state health care programs, and unaware of Defendants' fraudulent and illegal
6 practices, paid the claims submitted by health care providers and third party payers
7 in connection therewith.

8 529. Compliance with applicable Medicare, Medicaid and the various other
9 federal and state laws cited herein was an implied, and upon information and
10 belief, also an express condition of payment of claims submitted to the State of
11 Georgia in connection with Defendants' fraudulent and illegal practices.

12 530. Had the State of Georgia known that Defendants were violating the federal
13 and state laws cited herein, it would not have paid the claims submitted by health
14 care providers and third party payers in connection with Defendants' fraudulent
15 and illegal practices.

16 531. As a result of Defendants' violations of Ga. Code Ann. § 49-4-168.1, the
17 State of Georgia has been damaged in an amount far in excess of millions of
18 dollars exclusive of interest.

19 532. Defendants did not, within 30 days after it first obtained information as to
20 such violations, furnish such information to officials of the State responsible for
21 investigating false claims violations, did not otherwise fully cooperate with any
22 investigation of the violations, and have not otherwise furnished information to the
23 State regarding the claims for reimbursement at issue.

24 533. Relator are private persons with direct and independent knowledge of the
25 allegations of this Complaint, who have brought this action pursuant to Ga. Code
26 Ann., § 49-4-168.2(b) on behalf of themselves and the State of Georgia.

27 534. This Court is requested to accept supplemental jurisdiction of this related
28

1 state claim as it is predicated upon the exact same facts as the federal claim, and
2 merely asserts separate damage to the State of Georgia in the operation of its
3 Medicaid program.

4 535. Pursuant to the Georgia State False Medicaid Claims Act, the State of
5 Georgia and Relator are entitled to the following damages as against Defendants:

6 536. To the STATE OF GEORGIA:

7 537. Three times the amount of actual damages which the State of Georgia has
8 sustained as a result of Defendants' fraudulent and illegal practices;

9 538. A civil penalty on not less than \$5,500 and not more than \$ 11,000 for each
10 false claim which Defendants caused to be presented to the State of Georgia;

11 539. Prejudgment interest; and

12 540. All costs incurred in bringing this action.

13 541. To RELATOR:

14 542. The maximum amount allowed pursuant to Ga. Code Ann., § 49-4-168.2(i),
15 and/ or any other applicable provision of law;

16 543. Reimbursement for reasonable expenses which Relator incurred in
17 connection with this action;

18 544. An award of reasonable attorneys' fees and costs; and

19 545. Such further relief as this Court deems equitable and just.

20 **COUNT XVI**

21 **(Hawaii False Claims Act, Haw. Rev. Stat. § 661.21 *et seq.*)**

22 546. Relator re-allege and incorporate the allegations above as if fully set for
23 herein and further alleges as follows.

24 547. Additionally, Relator state that the course of conduct described in this
25 Complaint was a nationwide practice of Defendants. Defendants conduct business
26 in the State of Hawaii. Upon information and belief, Defendants' actions described
27 herein occurred in Hawaii as well.

1 548. This is a qui tam action brought by Relator and the State of Hawaii to
2 recover treble damages and civil penalties under the Hawaii False Claims Act,
3 Haw. Rev. Stat. § 661.21 *et seq.*

4 549. Haw. Rev. Stat. § 661-21(a) provides liability for any person who—

5 550. Knowingly presents, or causes to be presented, to an officer or employee of
6 the state a false or fraudulent claim for payment or approval;

7 551. Knowingly makes, uses, or causes to be made or used, a false record or
8 statement to get a false or fraudulent claim paid or approved by the state;

9 552. Conspires to defraud the state by getting a false or fraudulent claim allowed
10 or paid; or

11 553. Is a beneficiary of an inadvertent submission of a false claim to the State,
12 who subsequently discovers the falsity of the claim, and fails to disclose the false
13 claim to the State within a reasonable time after discovery of the false claim.

14 554. Defendants violated Haw. Rev. Stat. § 661.21(a) and knowingly caused
15 hundreds of thousands of false claims to be made, used and presented to the State
16 of Hawaii from at least 2005 to the present by its violation of federal and state
17 laws, including the Anti-Kickback Act, and Stark Act, as described herein.

18 555. The State of Hawaii, by and through the Hawaii Medicaid program and other
19 state health care programs, and unaware of Defendants' fraudulent and illegal
20 practices, paid the claims submitted by health care providers and third party payers
21 in connection therewith.

22 556. Compliance with applicable Medicare, Medicaid and the various other
23 federal state laws cited herein was an implied, and upon information and belief,
24 also an express condition of payment of claims submitted to the State of Hawaii in
25 connection with Defendants' fraudulent and illegal practices.

26 557. Had the State of Hawaii known that Defendants were violating the federal
27 and state laws cited herein, it would not have paid the claims submitted by health
28

1 care providers and third party payers in connection with Defendants' fraudulent
2 and illegal practices.

3 558. As a result of Defendants' violations of Haw. Rev. Stat. § 661-21(a) the
4 State of Hawaii has been damaged in an amount far in excess of millions of dollars
5 exclusive of interest.

6 559. Relator are private persons with direct and independent knowledge of the
7 allegations of this Complaint, who have brought this action pursuant to Haw. Rev.
8 Stat. § 661-25(a) on behalf of themselves and the State of Hawaii.

9 560. This Court is requested to accept supplemental jurisdiction of this related
10 state claim as it is predicated upon the exact same facts as the federal claim, and
11 merely asserts separate damage to the State of Hawaii in the operation of its
12 Medicaid program.

13 561. Pursuant to the Hawaii False Claims Act, the State of Hawaii and Relator are
14 entitled to the following damages as against Defendants:

15 562. To the STATE OF HAWAII:

16 563. Three times the amount of actual damages which the State of Hawaii has
17 sustained as a result of Defendants' fraudulent and illegal practices;

18 564. A civil penalty of not less than \$5,500 and not more than \$11,000 for each
19 false claim which Defendants caused to be presented to the State of Hawaii;

20 565. Prejudgment interest; and

21 566. All costs incurred in bringing this action.

22 567. To RELATOR:

23 568. The maximum amount allowed pursuant to Haw. Rev. Stat. § 661-27 and /or
24 any other applicable provision of law;

25 569. Reimbursement for reasonable expenses which Relator incurred in
26 connection with this action; and

27 570. Such further relief as this Court deems equitable and just.

COUNT XVII

(Illinois Whistleblower Reward and Protection Act, 740 ILCS 175 *et seq.*)

571. Relator re-allege and incorporate the allegations above as if fully set for herein and further alleges as follows.

572. Additionally, Relator state that the course of conduct described in this Complaint was a nationwide practice of Defendants. Defendants conduct business in the State of Illinois. Upon information and belief, Defendants' actions described herein occurred in Illinois as well.

573. This is a qui tam action brought by Relator and the State of Illinois to recover treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175 *et seq.*

574. 740 ILCS 175/3(a) provides liability for any person who—

575. knowingly presents, or causes to be presented, to an officer or employee of the State of a member of the Guard a false or fraudulent claim for payment or approval;

576. knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

577. Conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

578. In addition, 305 ILCS 5/8A-3(b) of the Illinois Public Aid Code (Vendor Fraud and Kickbacks) prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item of service for which payment may be made in whole or in part under the Illinois Medicaid program.

579. Defendants violated 305 ILCS 5/8A-3(b) from at least 2005 to the present by engaging in the fraudulent and illegal practices described herein.

580. Defendants furthermore violated 740 ILCS 175/3(a) and knowingly caused

1 hundreds of thousands of false claims to be made, used and presented to the State
2 of Illinois from at least 2005 to the present by its violation of federal and state
3 laws, including 305 ILCS 5/8A-3(b), the Anti-Kickback Act and the Stark Act, as
4 described herein.

5 581. The State of Illinois, by and through the Illinois Medicaid program and other
6 state health care programs, and unaware of Defendants' fraudulent and illegal
7 practices, paid the claims submitted by health care providers and third party payers
8 in connection therewith.

9 582. Compliance with applicable Medicare, Medicaid and the various other
10 federal and state laws cited herein with an implied, and upon information and
11 belief, also an express condition of payment of claims submitted to the State of
12 Illinois in connection with Defendants' fraudulent and illegal practices.

13 583. Had the State of Illinois known that Defendants were violating the federal
14 and state laws cited herein, it would not have paid the claims submitted by health
15 care providers and third party payers in connection with Defendants' fraudulent
16 and illegal practices.

17 584. As a result of Defendants' violations of 740 ILCS 175/3(a), the State of
18 Illinois has been damaged in an amount far in excess of millions of dollars
19 exclusive of interest.

20 585. Relator are private persons with direct and independent knowledge of the
21 allegation of this Complaint, who have brought this action pursuant to 740 ILCS
22 175/3(b) on behalf of themselves and the State of Illinois.

23 586. This court is requested to accept supplemental jurisdiction of this related
24 state claim as it is predicated upon the exact same facts as the federal claim, and
25 merely asserts separate damage to the State of Illinois in the operation of its
26 Medicaid program.

27 587. Pursuant to the Illinois Whistleblower Reward and Protection Act, the State
28

1 of Illinois and Relator are entitled to the following damages as against Defendants:

2 588. To the STATE OF ILLINOIS:

3 589. Three times the amount of actual damages which the State of Illinois has
4 sustained as a result of Defendants' fraudulent and illegal practices;

5 590. A civil penalty of not less than \$5,500 and not more than \$11,000 for each
6 false claim which Defendants caused to be presented to the State of Illinois;

7 591. Prejudgment interest; and

8 592. All costs incurred in bringing this action.

9 593. To RELATOR:

10 594. The maximum amount allowed pursuant to 740 ILCS/4(d) and/or any other
11 applicable provision of law;

12 595. Reimbursement for reasonable expenses which Relator incurred in
13 connection with this action;

14 596. An award of reasonable attorneys' fees and costs; and

15 597. Such further relief as this Court deems equitable and just.

16 **COUNT XVIII**

17 **(Illinois Insurance Claims Fraud Prevention Act, 740 ILCS 92/1 *et seq.*)**

18 598. Relator re-allege and incorporate the allegations above as if fully set for
19 herein and further alleges as follows.

20 599. This is a claim for treble damages and penalties under the Illinois Insurance
21 Claims Fraud Prevention Act.

22 600. By virtue of the acts described above, Defendants knowingly offered and/or
23 paid remuneration to physicians to induce the procurement of patients for
24 Defendants' drugs for which Defendants could cause the filing of claims for
25 payment from the patients' insurers. *See* 740 Ill. Comp. Stat. § 92/5(a).

26 601. Defendants knowingly presented or caused to be presented false or
27 fraudulent claims to the private insurers in Illinois, or for patients in Illinois those

1 insurers covered, for payment or approval in violation of each patient's private
2 health insurance contract.

3 602. By virtue of the acts described above, Defendants knowingly made, used, or
4 caused to be made or used false records and statements and omitted material facts
5 to induce the private insurers in Illinois, or for patients in Illinois covered by those
6 insurers, to approve or pay such false and fraudulent claims.

7 603. By virtue of the acts described above, the Defendants conspired to violate
8 the Illinois Insurance Claims Fraud Prevention Act and each patient's private health
9 insurance contract.

10 604. The private insurers in Illinois, or those insurers that covered patients in
11 Illinois, unaware of the falsity of the records, statements, and claims made, used,
12 presented, or caused to be presented by Defendants, paid and continue to pay the
13 claims that are non-payable as a result of Defendants' illegal conduct.

14 605. Defendants knowingly submitted and/or caused to be made or used false
15 records or false statements in order to avoid or decrease their respective obligations
16 to return overpayments to these private insurance companies.

17 606. By reason of Defendants' acts, these private insurance companies have been
18 damaged, and continue to be damaged, in a substantial amount to be determined at
19 trial.

20 607. Each claim for reimbursement that was a result of the Defendants' scheme
21 represents a false or fraudulent record or statement and a false or fraudulent claim
22 for payment.

23 608. The State of Illinois is entitled to the maximum penalty of \$10,000.00 for
24 each and every false or fraudulent claim, record, or statement made, 'used,
25 presented, or caused to be made, used, or presented by Defendants.

26 609. WHEREFORE, Relators request the following relief:

27 610. That this Court enter judgment against Defendants in an amount equal to
28

three times the amount of damages that the private insurance companies have sustained because of Defendants' actions, plus a civil penalty of not less than \$5,000.00 and not more than \$10,000.00 for each violation of 740 Ill. Comp. Stat. §§ 92/5(a) and (b);

611. No less than thirty percent (30%) of the proceeds of this action to the Relators if the State of Illinois elects to intervene, and no less than forty percent (40%) if it does not;

612. Relators' attorneys' fees, litigation and investigation costs, and other related expenses; and

613. Such other relief as the Court deems just and appropriate.

COUNT XIX

(Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5 *et seq.*)

614. Relator re-allege and incorporate the allegations above as if fully set for herein and further alleges as follows.

615. Additionally, Relator state that the course of conduct described in this Complaint was a nationwide practice of Defendants. Defendants conduct business in the State of Indiana. Upon information and belief, Defendants' actions described herein occurred in Indiana as well.

616. This is a qui tam action brought by Relator and the State of Indiana to recover treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5 *et seq.*

617. IC 5-11-5.5-2 provides liability for any person who—

618. presents a false claim to the state for payment or approval;

619. makes or uses a false record or statement to obtain payment or approval of a false claim from the state;

620. with intent to defraud the state, delivers less money or property to the state than the amount recorded on the certificate or receipt the person receives from the

1 state;

2 621. with intent to defraud the state, authorizes issuance of a receipt without
3 knowing that the information on the receipt is true;

4 622. receives public property as a pledge of an obligation on a debt from an
5 employee who is not lawfully authorized to sell or pledge the property;

6 623. makes or uses a false record or statement to avoid an obligation to pay or
7 transmit property to the state;

8 624. conspires with another person to perform an act described in subdivisions (a)
9 through (f); or

10 625. causes or induces another person to perform an act described in subdivisions
11 (a) through (f).

12 626. In addition, IC 12-15-24-1 & IC 12-15-24-2 prohibits the provision of a
13 kickback or bribe in connection with the furnishing of items or services or the
14 making or receipt of the payment under the Indiana Medicaid program.

15 627. Defendants violated IC 12-15-24-1 & IC 12-15-24-2 from at least 2005 to
16 the present by engaging in the fraudulent and illegal practices described herein.

17 628. Defendants furthermore violated IC 5-11-5.5-2 and knowingly caused
18 hundreds of thousands of false claims to be made, used and presented to the State
19 of Indiana from at least 2005 to the present by its violation of federal and state
20 laws, including IC 12-15-24-1 & IC 12-15-24-2, the Anti-Kickback Act and the
21 Stark Act, as described herein.

22 629. The State of Indiana, by and through the Indiana Medicaid program and
23 other state health care programs, and unaware of Defendants' fraudulent and illegal
24 practices, paid the claims submitted by health care providers and third party payers
25 in connection therewith.

26 630. Compliance with applicable Medicare, Medicaid and the various other
27 federal and state laws cited herein with an implied, and upon information and
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1 belief, also an express condition of payment of claims submitted to the State of
2 Indiana in connection with Defendants' fraudulent and illegal practices.

3 631. Had the State of Indiana known that Defendants were violating the federal
4 and state laws cited herein, it would not have paid the claims submitted by health
5 care providers and third party payers in connection with Defendants' fraudulent
6 and illegal practices.

7 632. As a result of Defendants' violations of IC 5-11-5.5-2, the State of Indiana
8 has been damaged in an amount far in excess of millions of dollars exclusive of
9 interest.

10 633. Relator are private persons with direct and independent knowledge of the
11 allegation of this Complaint, who have brought this action pursuant to IC 5-11-5.5-
12 4 on behalf of themselves and the State of Indiana.

13 634. This court is requested to accept supplemental jurisdiction of this related
14 state claim as it is predicated upon the exact same facts as the federal claim, and
15 merely asserts separate damage to the State of Indiana in the operation of its
16 Medicaid program.

17 635. Pursuant to the Indiana False Claims and Whistleblower Protection Act, the
18 State of Indiana and Relator are entitled to the following damages as against
19 Defendants:

20 636. To the STATE OF INDIANA:

21 637. Three times the amount of actual damages which the State of Indiana has
22 sustained as a result of Defendants' fraudulent and illegal practices;

23 638. A civil penalty of not less than \$5,000 and not more than \$10,000 for each
24 false claim which Defendants caused to be presented to the State of Indiana;

25 639. Prejudgment interest; and

26 640. All costs incurred in bringing this action.

27 641. To RELATOR:

1 642. The maximum amount allowed pursuant to IC 5-11-5.5-6 and/or any other
2 applicable provision of law;

3 643. Reimbursement for reasonable expenses which Relator incurred in
4 connection with this action;

5 644. An award of reasonable attorneys' fees and costs; and

6 645. Such further relief as this Court deems equitable and just.

7 **COUNT XX**

8 **(Iowa False Claims Act, Iowa Code § 685.1 *et seq.*)**

9 646. Relator re-allege and incorporate the allegations above as if fully set for
10 herein and further alleges as follows.

11 647. Additionally, Relator state that the course of conduct described in this
12 Complaint was a nationwide practice of Defendants. Defendants conduct business
13 in the State of Iowa. Upon information and belief, Defendants' actions described
14 herein occurred in Iowa as well.

15 648. This is a qui tam action brought by Relator and the State of Iowa to recover
16 treble damages and civil penalties under the Iowa False Claims Act, Iowa Code §
17 685.1 *et seq.*

18 649. Iowa Code § 685.2 provides liability for any person who—

19 650. Knowingly presents, or causes to be presented, a false or fraudulent claim
20 for payment or approval;

21 651. Knowingly makes, uses, or causes to be made or used, a false record or
22 statement material to a false or fraudulent claim;

23 652. Conspires to commit a violation of paragraphs (a), (b), (d)-(g);

24 653. Has possession, custody, or control of property or money used, or to be used,
25 by the state and knowingly delivers, or causes to be delivered, less than all of that
26 money or property;

27 654. Is authorized to make or deliver a document certifying receipt of property
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1 used, or to be used, by the state and, intending to defraud the state, makes or
2 delivers the receipt without completely knowing that the information on the receipt
3 is true;

4 655. Knowingly buys, or receives as a pledge of an obligation or debt, public
5 property from an officer or employee of the state, or a member of the Iowa national
6 guard, who lawfully may not sell or pledge property;

7 656. Knowingly makes, uses, or causes to be made or used, a false record or
8 statement material to an obligation to pay or transmit money or property to the
9 state, or knowingly conceals or knowingly and improperly avoids or decreases an
10 obligation to pay or transmit money or property to the state.

11 657. Defendants violated Iowa Code § 685.2 from at least 2005 to the present by
12 engaging in the fraudulent and illegal practices described herein.

13 658. Defendants furthermore violated Iowa Code § 685.2 and knowingly caused
14 hundreds of thousands of false claims to be made, used and presented to the State
15 of Iowa from at least 2005 to the present by its violation of federal and state laws,
16 including the Anti-Kickback Act and the Stark Act, as described herein.

17 659. The State of Iowa, by and through the Iowa Medicaid program and other
18 state health care programs, and unaware of Defendants' fraudulent and illegal
19 practices, paid the claims submitted by health care providers and third party payers
20 in connection therewith.

21 660. Compliance with applicable Medicare, Medicaid and the various other
22 federal and state laws cited herein with an implied, and upon information and
23 belief, also an express condition of payment of claims submitted to the State of
24 Iowa in connection with Defendants' fraudulent and illegal practices.

25 661. Had the State of Iowa known that Defendants were violating the federal and
26 state laws cited herein, it would not have paid the claims submitted by health care
27 providers and third party payers in connection with Defendants' fraudulent and
28

1 illegal practices.

2 662. As a result of Defendants' violations of Iowa Code § 685.2, the State of
3 Iowa has been damaged in an amount far in excess of millions of dollars exclusive
4 of interest.

5 663. Relator are private persons with direct and independent knowledge of the
6 allegation of this Complaint, who have brought this action pursuant to Iowa Code §
7 685.3(2)(a) on behalf of themselves and the State of Iowa.

8 664. This court is requested to accept supplemental jurisdiction of this related
9 state claim as it is predicated upon the exact same facts as the federal claim, and
10 merely asserts separate damage to the State of Iowa in the operation of its
11 Medicaid program.

12 665. Pursuant to the Iowa False Claims Act, the State of Iowa and Relator are
13 entitled to the following damages as against Defendants:

14 666. To the STATE OF IOWA:

15 667. Three times the amount of actual damages which the State of Iowa has
16 sustained as a result of Defendants' fraudulent and illegal practices;

17 668. A civil penalty for each false claim which Defendants caused to be presented
18 to the State of Iowa;

19 669. Prejudgment interest; and

20 670. All costs incurred in bringing this action.

21 671. To RELATOR:

22 672. The maximum amount allowed pursuant to Iowa Code § 685.3(4)(a)(1)
23 and/or any other applicable provision of law;

24 673. Reimbursement for reasonable expenses which Relator incurred in
25 connection with this action;

26 674. An award of reasonable attorneys' fees and costs; and

27 675. Such further relief as this Court deems equitable and just.

COUNT XXI

**(Louisiana Medical Assistance Programs Integrity Law, La Rev. Stat. Ann §
437.1 *et seq.*)**

676. Relator re-allege and incorporate the allegations above as if fully set for herein and further alleges as follows.

677. Additionally, Relator state that the course of conduct described in this Complaint was a nationwide practice of Defendants. Defendants conduct business in the State of Louisiana. Upon information and belief, Defendants' actions described herein occurred in Louisiana as well.

678. This is a qui tam action brought by Relator and the State of Louisiana to recover treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La Rev. Stat. Ann § 437.1 *et seq.*

679. La. Rev. Stat. Ann. § 438.3 provides –

680. No person shall knowingly present or cause to be presented a false or fraudulent claim;

681. No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance programs funds;

682. No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim.

683. In addition, La. Rev. Stat. Ann. § 438.2(A) prohibits the solicitation, receipt, offering or payment of any financial inducements, including kickbacks, bribes, rebated, etc., directly or indirectly, overtly or covertly, in cash or in kind, for furnishing health care goods or services paid for in whole or in part by the Louisiana medical assistance programs.

684. Defendants violated La. Rev. Stat. Ann § 438.2(A) from at least 2005 to the present by engaging in the fraudulent and illegal practices described herein.

1 685. Defendants furthermore violated La. Rev. Stat. Ann. § 438.3 and knowingly
2 caused hundreds of thousands of false claims to be made, used and presented to the
3 State of Louisiana from at least 2005 to the present by its violation of federal and
4 state laws, including La. Rev. Stat. Ann. § 438.2(A), the Anti-Kickback Act and
5 Stark Act, as described herein.

6 686. The State of Louisiana, by and through the Louisiana Medicaid program and
7 other state health care programs, and unaware of Defendants' fraudulent and illegal
8 practices, paid the claims submitted by health care providers and third party payers
9 in connection therewith.

10 687. Compliance with applicable Medicare, Medicaid and the various other
11 federal and state laws cited herein was an implied, and upon information and
12 belief, also an express condition of payment of claims submitted to the State of
13 Louisiana in connection with Defendants' fraudulent and illegal practices.

14 688. Had the State of Louisiana known that Defendants were violating the federal
15 and state laws cited herein, it would not have paid the claims submitted by health
16 care providers and third party payers in connection with Defendants' fraudulent
17 and illegal practices.

18 689. As a result of Defendants' violations of La. Rev. Stat. Ann. § 438.3 the State
19 of Louisiana has been damaged in an amount far in excess of millions of dollars
20 exclusive of interest.

21 690. Relator are private persons with direct and independent knowledge of the
22 allegations of this Complaint, who have brought this action pursuant to La. Rev.
23 Stat. Ann. § 439.1(A) on behalf of themselves and the State of Louisiana.

24 691. This Court is requested to accept supplemental jurisdiction of this related
25 state claim as it is predicated upon the exact same facts as the federal claim, and
26 merely asserts separate damage to the State of Louisiana in the operation of its
27 Medicaid program.

692. Pursuant to the Louisiana Medical Assistance Programs Integrity Law, the State of Louisiana and Relator are entitled to the following damages as against Defendants:

693. To the STATE OF LOUISIANA:

694. Three times the amount of actual damages which the State of Louisiana has sustained as a result of Defendants' fraudulent and illegal practices;

695. A civil penalty of not more than \$10,000 for each false claim which Defendants caused to be presented to the State of Louisiana;

696. Prejudgment interest; and

697. All costs incurred in bringing this action.

698. To RELATOR:

699. The maximum amount allowed pursuant to La. Rev. Stat. § 439.4(A) and/or any other applicable provision of law;

700. Reimbursement for reasonable expenses which Relator incurred in connection with this action;

701. An award or reasonable attorneys' fees and costs; and

702. Such further relief as this Court deems equitable and just.

COUNT XXII

(Maryland Medicaid False Claims Against State Health Plans and State Health Programs Act, Annotated Code of Maryland § 2-601 *et seq.*)

703. Relator re-allege and incorporate the allegations above as if fully set for herein and further alleges as follows.

704. Additionally, Relator state that the course of conduct described in this Complaint was a nationwide practice of Defendants. Defendants conduct business in the Commonwealth of Maryland. Upon information and belief, Defendants' actions described herein occurred in Maryland as well.

705. This is a qui tam action brought by Relator and the State of Maryland to

1 recover treble damages and civil penalties under the Maryland Medicaid False
2 Claims Against State Health Plans and State Health Programs Act, Annotated
3 Code of Maryland § 2-601 *et seq.*

4 706. Annotated Code of Maryland § 2-602 provides liability for any person who-

5 707. Knowingly presents or causes to be presented a false or fraudulent claim for
6 payment or approval;

7 708. Knowingly makes, uses, or causes to be made or used a false record or
8 statement material to a false or fraudulent claim;

9 709. Conspires to commit a violation under this subtitle;

10 710. Has possession, custody, or control of money or other property used by or on
11 behalf of the State under a State health plan or a State health program and
12 knowingly delivers or causes to be delivered to the State less than all of that money
13 or other property;

14 711. Knowingly makes any other false or fraudulent claim against a State health
15 plan or a State health program.

16 712. Defendants violated the Annotated Code of Maryland § 2-602 from at least
17 2005 to the present by engaging in the fraudulent and illegal practices described
18 herein.

19 713. Defendants furthermore violated the Annotated Code of Maryland § 2-602
20 and knowingly caused thousands of false claims to be made, used and presented to
21 the State of Maryland from at least 2005 to the present by its violation of federal
22 and state laws, including the Anti-Kickback Act, and the Stark Act, as described
23 herein.

24 714. The State of Maryland, by and through the State of Maryland Medicaid
25 program and other state health care programs, and unaware of Defendants'
26 fraudulent and illegal practices, paid the claims submitted by health care providers
27 and third payers in connection therewith.

1 715. Compliance with applicable Medicare, Medicaid and the various other
2 federal and state laws cited herein was an implied, and upon information and
3 belief, also an express condition of payment of claims submitted to the State of
4 Maryland in connection with Defendants' fraudulent and illegal practices.

5 716. Had the State of Maryland known that Defendants were violating the federal
6 and state laws cited herein, it would not have paid the claims submitted by health
7 care providers and third party payers in connection with Defendants' fraudulent
8 and illegal practices.

9 717. As a result of Defendants' violations of the Annotated Code of Maryland §
10 2-602 the State of Maryland has been damaged in an amount far in excess of
11 millions of dollars exclusive of interest.

12 718. Relator have direct and independent knowledge of the allegations of this
13 Complaint, who have brought this action pursuant to the Annotated Code of
14 Maryland § 2-604 on behalf of themselves and the State of Maryland.

15 719. This Court is requested to accept supplemental jurisdiction of this related
16 state claim as it is predicated upon the exact same facts as the federal claim, and
17 merely asserts separate damage to the State of Maryland in the operation of its
18 Medicaid program.

19 720. Pursuant to the Maryland Medicaid False Claims Against State Health Plans
20 and State Health Programs Act, the State of Maryland and Relator are entitled to
21 the following damages as against Defendants:

22 721. To the STATE OF MARYLAND:

23 722. Three times the amount of actual damages which the State of Maryland has
24 sustained as a result of Defendants' fraudulent and illegal practices;

25 723. A civil penalty of not less than the amount of the actual damages the State
26 health plan or State health program incurs as a result of the violation, and not more
27 than \$10,000 for each false claim which Defendants caused to be presented to the

1 State of Maryland;

2 724. Prejudgment interest; and

3 725. All costs incurred in bringing this action.

4 726. To RELATOR:

5 727. The maximum amount allowed pursuant to the Annotated Code of Maryland
6 § 2-605 and /or any other applicable provision of law;

7 728. Reimbursement for reasonable expenses which Relator incurred in
8 connection with this action;

9 729. An award of reasonable attorneys' fees and costs; and

10 730. Such further relief as this court deems equitable and just.

11 **COUNT XXIII**

12 **(Massachusetts False Claims Act, Mass. Gen. Laws Ann. Chap 12 § 5(A) *et***
13 ***seq.*)**

14 731. Relator re-allege and incorporate the allegations above as if fully set for
15 herein and further alleges as follows.

16 732. Additionally, Relator state that the course of conduct described in this
17 Complaint was a nationwide practice of Defendants. Defendants conduct business
18 in the Commonwealth of Massachusetts. Upon information and belief, Defendants'
19 actions described herein occurred in Massachusetts as well.

20 733. This is a qui tam action brought by Relator and State of Massachusetts for
21 treble damages and penalties under Massachusetts False Claims Act, Mass. Gen.
22 Laws Ann. Chap 12 § 5(A) *et seq.*

23 734. Mass. Gen. Laws Ann. Chap 12 § 5B provides liability for any person
24 who—

25 735. Knowingly presents, or causes to be presented, a false or fraudulent claim
26 for payment or approval;

27 736. Knowingly makes, uses, or causes to be made or used, a false record or
28

1 statement to obtain payment or approval of a claim by the commonwealth or any
2 political subdivision thereof;

3 737. Conspires to defraud the commonwealth or any political subdivision thereof
4 through the allowance or payment of a fraudulent claim;

5 738. Is a beneficiary of an inadvertent submission of a false claim to the common
6 wealth or political subdivision thereof, subsequently discovers the falsity of the
7 claim, and fails to disclose the false claim to the commonwealth or political
8 subdivision within a reason able time after discovery of the false claim.

9 739. In addition, Mass. Gen. Laws Ann. Chap. 118E § 41 prohibits the
10 solicitation, receipt or offering of any remuneration, including any bribe ore rebate,
11 directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing
12 any good, service or item for which payment may be made in whole or in part
13 under the Massachusetts Medicaid program.

14 740. Defendants violated Mass. Gen. Laws Ann. Chap. 118E § 41 from at least
15 2005 to the present by engaging in the fraudulent and illegal practices described
16 herein.

17 741. Defendants furthermore violated Mass. Gen. Laws Ann. Chap 12 § 5B and
18 knowingly caused hundreds of thousands of false claims to be made, used and
19 presented to the State of Massachusetts from at least 2005 to the present by its
20 violation of federal and state laws, including Mass. Gen. Laws Ann. Chap. 118E §
21 41, the Anti-Kickback Act and the Stark Act, as described herein.

22 742. The State of Massachusetts, by and through the Massachusetts Medicaid
23 program and other state health care programs, and unaware of Defendants'
24 fraudulent and illegal practices, paid the claims submitted by health care providers
25 and third party payers in connection therewith.

26 743. Compliance with applicable Medicare, Medicaid and the various other
27 federal and state laws cited herein was an implied, and upon information and
28

1 belief, also an express condition of payment of claims submitted to the State of
2 Massachusetts in connection with Defendants' fraudulent and illegal practices.

3 744. Had the State of Massachusetts known that Defendants were violating the
4 federal and state laws cited herein, it would not have paid the claims submitted by
5 health care providers and third party payers in connection with Defendants'
6 fraudulent and illegal practices.

7 745. As a result of Defendants' violations of Mass. Gen. Laws Ann. Chap. 12 §
8 5B the State of Massachusetts has been damaged in an amount far in excess of
9 millions of dollars exclusive of interest.

10 746. Relator are private persons with direct and independent knowledge of the
11 allegations of the Compliant, who have brought this action pursuant to Mass. Gen.
12 Laws Ann Chap. 12 § 5(c)(2) on behalf of themselves and the State of
13 Massachusetts.

14 747. This Court is requested to accept supplemental jurisdiction of this related
15 state claim as it is predicated upon that exact same facts as the federal claim, and
16 merely asserts separate damage to the State of Massachusetts in the operation of its
17 Medicaid program.

18 748. Pursuant to the Massachusetts False Claims Act, the State of Massachusetts
19 and Relator are entitled to the following damages as against Defendants:

20 749. To the STATE OF MASSACHUSETTS:

21 750. Three times the amount of actual damages which that State of Massachusetts
22 has sustained as a result of Defendants' fraudulent and illegal practices;

23 751. A civil penalty of not less than \$5,500 and not more than \$11,000 for each
24 false claim which Defendants caused to be presented to the State of Massachusetts;

25 752. Prejudgment interest; and

26 753. All costs incurred in bringing this action.

27 754. To RELATOR:

1 755. The maximum amount allowed pursuant to Mass. Gen. Laws Ann. Chap. 12
2 § 5F and/or any other applicable provision of law;

3 756. Reimbursement for reasonable expenses which Relator incurred in
4 connection with this action;

5 757. An award of reasonable attorneys' fees and costs; and

6 758. Such further relief as this court deems equitable and just.

7 **COUNT XXIV**

8 **(Michigan Medicaid False Claim Act, M.C.L.A. 400.601 *et seq.*)**

9 759. Relator re-allege and incorporate the allegations above as if fully set for
10 herein and further alleges as follows.

11 760. Additionally, Relator state that the course of conduct described in this
12 Complaint was a nationwide practice of Defendants. Defendants conduct business
13 in Michigan. Upon information and belief, Defendants' actions described herein
14 occurred in Michigan as well.

15 761. This is a qui tam action brought by Relator and State of Michigan for treble
16 damages and penalties under Michigan Medicaid False Claim Act, M.C.L.A.
17 400.601 *et seq.*

18 762. M.C.L.A. 400.607 provides liability for any person who, among other
19 things—

20 763. Causes to be made or presented to an employee or officer of this state a
21 claim under the social welfare act, Act No. 280 of the Public Acts of 1939, as
22 amended, being sections 400.1 to 400.121 of the Michigan Compiled Laws, upon
23 or against the state, knowing the claim to be false.

24 764. Presents or causes to be made or presented a claim under the social welfare
25 act, Act No. 280 of the Public Acts of 1939, which he or she knows falsely
26 represents that the goods or services for which the claim is made were medically
27 necessary in accordance with professionally accepted standards.

1 765. In addition, M.C.L.A. 400.604 prohibits the solicitation, receipt or offering
2 of a kickback or bribe in connection with the furnishing of goods or services for
3 which payment is or may be made in whole or in part pursuant to the Michigan
4 Medicaid program.

5 766. Defendants violated M.C.L.A. 400.604 from at least 2005 to the present by
6 engaging in the fraudulent and illegal practices described herein.

7 767. Defendants furthermore violated M.C.L.A. 400.607 and knowingly caused
8 hundreds of thousands of false claims to be made, used and presented to the State
9 of Michigan from at least 2005 to the present by its violation of federal and state
10 laws, including M.C.L.A. 400.604, the Anti-Kickback Act and the Stark Act, as
11 described herein.

12 768. The State of Michigan, by and through the Michigan Medicaid program and
13 other state health care programs, and unaware of Defendants' fraudulent and illegal
14 practices, paid the claims submitted by health care providers and third party payers
15 in connection therewith.

16 769. Compliance with applicable Medicare, Medicaid and the various other
17 federal and state laws cited herein was an implied, and upon information and
18 belief, also an express condition of payment of claims submitted to the State of
19 Michigan in connection with Defendants' fraudulent and illegal practices.

20 770. Had the State of Michigan known that Defendants were violating the federal
21 and state laws cited herein, it would not have paid the claims submitted by health
22 care providers and third party payers in connection with Defendants' fraudulent
23 and illegal practices.

24 771. As a result of Defendants' violations of M.C.L.A. 400.607 the State of
25 Michigan has been damaged in an amount far in excess of millions of dollars
26 exclusive of interest.

27 772. Relator are private persons with direct and independent knowledge of the
28

1 allegations of the Compliant, who have brought this action pursuant to M.C.L.A.
2 400.610a on behalf of themselves and the State of Michigan.

3 773. This Court is requested to accept supplemental jurisdiction of this related
4 state claim as it is predicated upon that exact same facts as the federal claim, and
5 merely asserts separate damage to the State of Michigan in the operation of its
6 Medicaid program.

7 774. Pursuant to the Michigan Medicaid False Claim Act, the State of Michigan
8 and Relator are entitled to the following damages as against Defendants:

9 775. To the STATE OF MICHIGAN:

10 776. Three times the amount of actual damages which that State of Michigan has
11 sustained as a result of Defendants' fraudulent and illegal practices;

12 777. A civil penalty of not less than \$5,000 and not more than \$10,000 for each
13 false claim which Defendants caused to be presented to the State of Michigan;

14 778. Prejudgment interest; and

15 779. All costs incurred in bringing this action.

16 780. To RELATOR:

17 781. The maximum amount allowed pursuant to M.C.L.A. 400.610a(9) and/or
18 any other applicable provision of law;

19 782. Reimbursement for reasonable expenses which Relator incurred in
20 connection with this action;

21 783. An award of reasonable attorneys' fees and costs; and

22 784. Such further relief as this court deems equitable and just.

23 **COUNT XXV**

24 **(Minnesota False Claims Act, (Minnesota Statutes § 15C.01 *et seq.*)**

25 785. Relator re-allege and incorporate the allegations above as if fully set for
26 herein and further alleges as follows.

27 786. Additionally, Relator state that the course of conduct described in this

1 Complaint was a nationwide practice of Defendants. Defendants conduct business
2 in Minnesota. Upon information and belief, Defendants' actions described herein
3 occurred in Minnesota as well.

4 787. This is a qui tam action brought by Relator and the State of Minnesota to
5 recover treble damages and civil penalties under the Minnesota False Claims Act,
6 Minnesota Statutes § 15C.01 *et seq.*

7 788. Minnesota Statutes § 15C.02 provides liability for any person who-

8 789. Knowingly presents, or causes to be presented, to an officer or employee of
9 the state or a political subdivision a false or fraudulent claim for payment or
10 approval;

11 790. Knowingly makes or uses, or causes to be made or used, a false record or
12 statement to get a false or fraudulent claim paid or approved by the state or a
13 political subdivision;

14 791. Knowingly conspires to either present a false or fraudulent claim to the state
15 or a political subdivision for payment or approval or makes, uses, or causes to be
16 made or used a false record or statement to obtain payment or approval of a false
17 or fraudulent claim.

18 792. Defendants violated Minnesota Statutes § 15C.02 from at least 2005 to the
19 present by engaging in the fraudulent and illegal practices described herein.

20 793. Defendants furthermore violated Minnesota Statutes § 15C.02 and
21 knowingly caused thousands of false claims to be made, used and presented to the
22 State of Minnesota from at least 2005 to the present by its violation of federal and
23 state laws, including the Anti-Kickback Act, and the Stark Act, as described
24 herein.

25 794. The State of Minnesota, by and through the State of Minnesota Medicaid
26 program and other state health care programs, and unaware of Defendants'
27 fraudulent and illegal practices, paid the claims submitted by health care providers
28

1 and third payers in connection therewith.

2 795. Compliance with applicable Medicare, Medicaid and the various other
3 federal and state laws cited herein was an implied, and upon information and
4 belief, also an express condition of payment of claims submitted to the State of
5 Minnesota in connection with Defendants' fraudulent and illegal practices.

6 796. Had the State of Minnesota known that Defendants were violating the
7 federal and state laws cited herein, it would not have paid the claims submitted by
8 health care providers and third party payers in connection with Defendants'
9 fraudulent and illegal practices.

10 797. As a result of Defendants' violations of Minnesota Statutes § 15C.02 the
11 State of Minnesota has been damaged in an amount far in excess of millions of
12 dollars exclusive of interest.

13 798. Relator have direct and independent knowledge of the allegations of this
14 Complaint, who have brought this action pursuant to Minnesota Statutes § 15C.05
15 on behalf of themselves and the State of Minnesota.

16 799. This Court is requested to accept supplemental jurisdiction of this related
17 state claim as it is predicated upon the exact same facts as the federal claim, and
18 merely asserts separate damage to the State of Minnesota in the operation of its
19 Medicaid program.

20 800. Pursuant to the Minnesota False Claims Act, the State of Minnesota and
21 Relator are entitled to the following damages as against Defendants:

22 801. To the STATE OF MINNESOTA:

23 802. Three times the amount of actual damages which the State of Minnesota has
24 sustained as a result of Defendants' fraudulent and illegal practices;

25 803. A civil penalty of not less than \$5,500, and not more than \$11,000 for each
26 false claim which Defendants caused to be presented to the State of Minnesota;

27 804. Prejudgment interest; and

1 805. All costs incurred in bringing this action.

2 806. To RELATOR:

3 807. The maximum amount allowed pursuant to Minnesota Statutes § 15C.12 and
4 § 15C.13 and /or any other applicable provision of law;

5 808. Reimbursement for reasonable expenses which Relator incurred in
6 connection with this action;

7 809. An award of reasonable attorneys' fees and costs; and

8 810. Such further relief as this court deems equitable and just.

9 **COUNT XXVI**

10 **(Missouri Health Care Payment Fraud and Abuse Act, Missouri Revised**
11 **Statutes § 191.900 et seq.)**

12 811. Relator re-alleges and incorporates by reference each of the paragraphs
13 above as if fully set forth herein and further alleges as follows.

14 812. Additionally, Relator states that the course of conduct described in this
15 Complaint was a nationwide practice of Defendants. Defendants conduct business
16 in the State of Missouri. Upon information and belief, Defendants' actions
17 described herein occurred in the State of Missouri as well.

18 813. This is a qui tam action brought by Relator and the State of Missouri to
19 recover treble damages and civil penalties under the Missouri Health Care Payment
20 Fraud And Abuse Act, Missouri Revised Statutes § 191.900 et seq.

21 814. The Missouri Health Care Payment Fraud And Abuse Act § 191-905(1)
22 provides liability for any person –

23 815. Knowingly presenting to a health care payer a claim for a health care
24 payment that falsely represents that the health care for which the health care
25 payment is claimed was medically necessary, if in fact it was not;

26 816. Knowingly concealing the occurrence of any event affecting an initial or
27 continued right under a medical assistance program to have a health care payment

1 made by a health care payer for providing health care;

2 817. Knowingly concealing or failing to disclose any information with the intent
3 to obtain a health care payment to which the health care provider or any other
4 health care provider is not entitled, or to obtain a health care payment in an amount
5 greater than that which the health care provider or any other health care provider is
6 entitled.

7 818. Knowingly presenting a claim to a health care payer that falsely indicates
8 that any particular health care was provided to a person or persons, if in fact health
9 care of lesser value than that described in the claim was provided.

10 819. The Missouri Health Care Payment Fraud And Abuse Act § 191-905(2)
11 provides liability if any person shall knowingly solicit or receive any remuneration,
12 including any kickback, bribe, or rebate, directly or indirectly, overtly or covertly,
13 in cash or in kind in return for -

14 820. Referring another person to a health care provider for the furnishing or
15 arranging for the furnishing of any health care; or

16 821. Purchasing, leasing, ordering or arranging for or recommending purchasing,
17 leasing or ordering any health care.

18 822. The Missouri Health Care Payment Fraud And Abuse Act § 191-905(3)
19 provides liability if any person shall knowingly offer or pay any remuneration,
20 including any kickback, bribe, or rebate, directly or indirectly, overtly or covertly,
21 in cash or in kind, to any person to induce such person to refer another person to a
22 health care provider for the furnishing or arranging for the furnishing of any health
23 care.

24 823. Defendants violated the Missouri Health Care Payment Fraud and Abuse
25 Act § 191-905(1) & (2) & (3) from at least 2001 to the present by engaging in the
26 fraudulent and illegal practices described herein.

27 824. Defendants furthermore violated Missouri Health Care Payment Fraud And
28

1 Abuse Act § 191-905(1) & (2) & (3) and knowingly caused thousands of false
2 claims to be made, used and presented to Missouri from at least 2005 to the present
3 by its violation of federal and state laws, including Missouri Revised Statutes
4 §191-905(3), the Anti-Kickback Act and Stark Act Requirements, as described
5 herein.

6 825. Missouri, by and through the Missouri Medicaid program and other state
7 health care programs, and unaware of Defendants' fraudulent and illegal practices,
8 paid the claims submitted by health care providers and third payers in connection
9 therewith.

10 826. Compliance with applicable Medicare, Medicaid and the various other
11 federal and state laws cited herein was an implied, and upon information and
12 belief, also an express condition of payment of claims submitted to Missouri in
13 connection with Defendants' fraudulent and illegal practices.

14 827. Had the State of Missouri known that Defendants were violating the federal
15 and state laws cited herein, it would not have paid the claims submitted by health
16 care providers and third party payers in connection with Defendants' fraudulent and
17 illegal practices.

18 828. As a result of Defendants' violations of § 191-905(1) & (2) & (3), the State
19 of Missouri has been damaged in an amount far in excess of millions of dollars
20 exclusive of interest.

21 829. Relator is a private person with direct and independent knowledge of the
22 allegations of this Complaint, who has brought this action pursuant to Missouri
23 Revised Statutes § 191.907 on behalf of themselves and the State of Missouri.

24 830. This Court is requested to accept supplemental jurisdiction of this related
25 state claim as it is predicated upon the exact same facts as the federal claim, and
26 merely asserts separate damage to the State of Missouri in the operation of its
27 Medicaid program.

831. Pursuant to the Missouri Health Care Payment Fraud And Abuse Act, the State of Missouri and Relator is entitled to the following damages as against Defendants:

832. To the STATE OF MISSOURI:

833. Three times the amount of actual damages which the State of Missouri has sustained as a result of Defendants' fraudulent and illegal practices;

834. A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Defendants caused to be presented to the State of Missouri;

835. Prejudgment interest; and

836. All costs incurred in bringing this action.

837. To RELATOR:

838. The maximum amount allowed pursuant to Missouri Revised Statutes § 191.907 and /or any other applicable provision of law;

839. Reimbursement for reasonable expenses which Relator incurred in connection with this action;

840. An award of reasonable attorneys' fees and costs; and

841. Such further relief as this court deems equitable and just.

COUNT XXVII

(Montana False Claims Act, MT ST 17-8-401 *et seq.*)

842. Relator re-allege and incorporate the allegations above as if fully set for herein and further alleges as follows.

843. Additionally, Relator state that the course of conduct described in this Complaint was a nationwide practice of Defendants. Defendants conduct business in Montana. Upon information and belief, Defendants' actions described herein occurred in Montana as well.

844. This is a qui tam action brought by Relator and State of Montana for treble damages and penalties under Montana False Claims Act, MT ST 17-8-401 *et seq.*

1 845. MT ST 17-8-403 provides liability for any person who—

2 846. knowingly presenting or causing to be presented to an officer or employee of
3 the governmental entity a false claim for payment or approval;

4 847. knowingly making, using, or causing to be made or used a false record or
5 statement to get a false claim paid or approved by the governmental entity;

6 848. conspiring to defraud the governmental entity by getting a false claim
7 allowed or paid by the governmental entity.

8 849. In addition, MT ST 45-6-313 prohibits the solicitation, receipt or offering
9 any remuneration, including but not limited to a kickback, bribe, or rebate, other
10 than an amount legally payable under the medical assistance program, for
11 furnishing services or items for which payment may be made under the Montana
12 Medicaid program.

13 850. Defendants violated MT ST 45-6-313 from at least 2005 to the present by
14 engaging in the fraudulent and illegal practices described herein.

15 851. Defendants furthermore violated MT ST 17-8-403 and knowingly caused
16 hundreds of thousands of false claims to be made, used and presented to the State
17 of Montana from at least 2005 to the present by its violation of federal and state
18 laws, including MT ST 45-6-313, the Anti-Kickback Act and the Stark Act, as
19 described herein.

20 852. The State of Montana, by and through the Montana Medicaid program and
21 other state health care programs, and unaware of Defendants' fraudulent and illegal
22 practices, paid the claims submitted by health care providers and third party payers
23 in connection therewith.

24 853. Compliance with applicable Medicare, Medicaid and the various other
25 federal and state laws cited herein was an implied, and upon information and
26 belief, also an express condition of payment of claims submitted to the State of
27 Montana in connection with Defendants' fraudulent and illegal practices.

1 854. Had the State of Montana known that Defendants were violating the federal
2 and state laws cited herein, it would not have paid the claims submitted by health
3 care providers and third party payers in connection with Defendants' fraudulent
4 and illegal practices.

5 855. As a result of Defendants' violations of MT ST 17-8-403 the State of
6 Montana has been damaged in an amount far in excess of millions of dollars
7 exclusive of interest.

8 856. Relator are private persons with direct and independent knowledge of the
9 allegations of the Compliant, who have brought this action pursuant to MT ST 17-
10 8-406 on behalf of themselves and the State of Montana.

11 857. This Court is requested to accept supplemental jurisdiction of this related
12 state claim as it is predicated upon that exact same facts as the federal claim, and
13 merely asserts separate damage to the State of Montana in the operation of its
14 Medicaid program.

15 858. Pursuant to the Montana False Claims Act, the State of Montana and Relator
16 are entitled to the following damages as against Defendants:

17 859. To the STATE OF MONTANA:

18 860. Three times the amount of actual damages which that State of Montana has
19 sustained as a result of Defendants' fraudulent and illegal practices;

20 861. A civil penalty of between \$5,500 and \$11,000 (adjusted for inflation) for
21 each false claim which Defendants caused to be presented to the State of Montana;

22 862. Prejudgment interest; and

23 863. All costs incurred in bringing this action.

24 864. To RELATOR:

25 865. The maximum amount allowed pursuant to MT ST 17-8-410 and/or any
26 other applicable provision of law;

27 866. Reimbursement for reasonable expenses which Relator incurred in
28

1 connection with this action;

2 867. An award of reasonable attorneys' fees and costs; and

3 868. Such further relief as this Court deems equitable and just.

4 **COUNT XXVIII**

5 **(Nevada False Claims Act, N.R.S. § 357.010 *et seq.*)**

6 869. Relator re-allege and incorporate the allegations above as if fully set for
7 herein and further alleges as follows.

8 870. Additionally, Relator state that the course of conduct described in this
9 Complaint was a nationwide practice of Defendants. Defendants conduct business
10 in the State of Nevada. Upon information and belief, Defendants' actions described
11 herein occurred in Nevada as well.

12 871. This is a qui tam action brought by Relator and the State of Nevada to
13 recover treble damages and civil penalties under the Nevada False Claims Act,
14 N.R.S. § 357.010 *et. seq.*

15 872. N.R.S. § 357.040(1) provides liability for any person who—

16 873. Knowingly presents or causes to be presented a false claim for payment or
17 approval;

18 874. Knowingly makes or uses, or causes to be made or used, a false record or
19 statement to obtain payment or approval of a false claim;

20 875. Conspires to defraud by obtaining allowance or payment of a false claim;

21 876. Is a beneficiary of an inadvertent submission of a false claim and, after
22 discovering the falsity of the claim, fails to disclose the falsity to the state or
23 political subdivision within a reasonable time.

24 877. In addition, N.R.S. § 422.560 prohibits the solicitation, acceptance or receipt
25 of anything of value in connection with the provision of medical goods or services
26 for which payment may be made in whole or in part under the Nevada Medicaid
27 program.

1 878. Defendants violated N.R.S. § 422.560 from at least 2005 to the present by
2 engaging in the fraudulent and illegal practices described herein.

3 879. Defendants furthermore violated N.R.S. § 357.040(1) and knowingly caused
4 hundreds of thousands of false claims to be made, used and presented to the State
5 of Nevada from at least 2005 to the present by its violation of federal and state
6 laws, including N.R.S. § 422.560, the Anti-Kickback Act and the Stark Act, as
7 described herein.

8 880. The State of Nevada, by and through the Nevada Medicaid program and
9 other health care programs, and unaware of Defendants' fraudulent and illegal
10 practices, paid the claims submitted by health care providers and third party payers
11 in connection therewith.

12 881. Compliance with applicable Medicare, Medicaid and the various other
13 federal and state laws cited herein was an implied, and upon information and
14 belief, also an express condition of payment of claims submitted to the State of
15 Nevada in connection with Defendants' fraudulent and illegal practices.

16 882. Had the State of Nevada known that Defendants were violating the federal
17 and state laws cited herein, it would not have paid the claims submitted by health
18 care providers and third party payers in connection with Defendants' fraudulent
19 and illegal practices.

20 883. As a result of Defendants' violations of N.R.S. § 357.040(1) the State of
21 Nevada has been damaged in an amount far in excess or millions of dollars
22 exclusive of interest.

23 884. Relator are private persons with direct and independent knowledge of the
24 allegations of this Complaint, who have brought this action pursuant to N.R.S. §
25 357.080(1) on behalf of themselves and the State of Nevada.

26 885. This Court is requested to accept supplemental jurisdiction of this related
27 state claim as it is predicated upon the exact same facts as the federal claim, and
28

1 merely asserts separate damage to the State of Nevada in the operation of its
2 Medicaid program.

3 886. Pursuant to the Nevada False Claims Act, the State of Nevada and Relator
4 are entitled to the following damages as against Defendants:

5 887. To the STATE OF NEVADA:

6 888. Three times the amount of actual damages which the State of Nevada has
7 sustained as a result of Defendants' fraudulent and illegal practices;

8 889. A civil penalty of not less than \$5,500 and not more than \$11,000 for each
9 false claim which Defendants caused to be presented to the State of Nevada;

10 890. Prejudgment interest; and

11 891. All costs incurred in bringing this action.

12 892. To RELATOR:

13 893. The maximum amount allowed pursuant to N.R.S § 357.210 and/or any
14 other applicable provision of law;

15 894. Reimbursement for reasonable expenses which Relator incurred in
16 connection with this action;

17 895. An award of reasonable attorneys' fees and costs; and

18 896. Such further relief as this Court deems equitable and just.

19 **COUNT XXIX**

20 **(New Jersey False Claims Act, N.J.S.A. 2A:32C-1 *et seq.*)**

21 897. Relator re-allege and incorporate the allegations above as if fully set for
22 herein and further alleges as follows.

23 898. Additionally, Defendants conduct business in the New Jersey. Upon
24 information and belief, Defendants' actions described herein occurred in New
25 Jersey as well.

26 899. This is a qui tam action brought by Relator and State of New Jersey for
27 treble damages and penalties under New Jersey False Claims Act, N.J.S.A.

1 2A:32C-1 *et seq.*

2 900. N.J.S.A. 2A:32C-3 provides liability for any person who—

3 901. Knowingly presents or causes to be presented to an employee, officer or
4 agent of the State, or to any contractor, grantee, or other recipient of State funds, a
5 false or fraudulent claim for payment or approval;

6 902. Knowingly makes, uses, or causes to be made or used a false record or
7 statement to get a false or fraudulent claim paid or approved by the State;

8 903. Conspires to defraud the State by getting a false or fraudulent claim allowed
9 or paid by the State.

10 904. In addition, N.J.S.A. 30:4D-17 prohibits solicitation, offers, or receipt of any
11 kickback, rebate or bribe in connection with the furnishing of items or services for
12 which payment is or may be made in whole or in part under the New Jersey
13 Medicaid program, or the furnishing of items or services whose cost is or may be
14 reported in whole or in part in order to obtain benefits or payments under New
15 Jersey Medicaid.

16 905. Defendants violated N.J.S.A. 30:4D-17 from at least 2005 to the present by
17 engaging in the fraudulent and illegal practices described herein.

18 906. Defendants furthermore violated N.J.S.A. 2A:32C-3 and knowingly caused
19 hundreds of thousands of false claims to be made, used and presented to the State
20 of Nevada from at least 2005 to the present by its violation of federal and state
21 laws, including N.J.S.A. 30:4D-17, the Anti-Kickback Act and the Stark Act, as
22 described herein.

23 907. The State of New Jersey, by and through the New Jersey Medicaid program
24 and other state health care programs, and unaware of Defendants' fraudulent and
25 illegal practices, paid the claims submitted by health care providers and third party
26 payers in connection therewith.

27 908. Compliance with applicable Medicare, Medicaid and the various other

1 federal and state laws cited herein was an implied, and upon information and
2 belief, also an express condition of payment of claims submitted to the State of
3 New Jersey in connection with Defendants' fraudulent and illegal practices.

4 909. Had the State of New Jersey known that Defendants were violating the
5 federal and state laws cited herein, it would not have paid the claims submitted by
6 health care providers and third party payers in connection with Defendants'
7 fraudulent and illegal practices.

8 910. As a result of Defendants' violations of N.J.S.A. 2A:32C-3 the State of New
9 Jersey has been damaged in an amount far in excess of millions of dollars
10 exclusive of interest.

11 911. Relator are private persons with direct and independent knowledge of the
12 allegations of the Compliant, who have brought this action pursuant to N.J.S.A.
13 2A:32C-5 on behalf of themselves and the State of New Jersey.

14 912. This Court is requested to accept supplemental jurisdiction of this related
15 state claim as it is predicated upon that exact same facts as the federal claim, and
16 merely asserts separate damage to the State of New Jersey in the operation of its
17 Medicaid program.

18 913. Pursuant to the New Jersey False Claims Act, the State of New Jersey and
19 Relator are entitled to the following damages as against Defendants:

20 914. To the STATE OF NEW JERSEY:

21 915. Three times the amount of actual damages which that State of New Jersey
22 has sustained as a result of Defendants' fraudulent and illegal practices;

23 916. A civil penalty of not less than \$5,500 and not more than \$11,000 for each
24 false claim which Defendants caused to be presented to the State of New Jersey;

25 917. Prejudgment interest; and

26 918. All costs incurred in bringing this action.

27 919. To RELATOR:

1 920. The maximum amount allowed pursuant to N.J.S.A. 2A:32C-7 and/or any
2 other applicable provision of law;

3 921. Reimbursement for reasonable expenses which Relator incurred in
4 connection with this action;

5 922. An award of reasonable attorneys' fees and costs; and

6 923. Such further relief as this Court deems equitable and just.

7 **COUNT XXX**

8 **(New Mexico Medicaid False Claims Act, and New Mexico Fraud Against**
9 **Taxpayers Act, N. M. S. A. 1978, § 27-14-1 *et seq.*, and N. M. S. A. 1978, § 44-**
10 **9-1 *et seq.*)**

11 924. Relator re-allege and incorporate the allegations above as if fully set for
12 herein and further alleges as follows.

13 925. Additionally, Relator state that the course of conduct described in this
14 Complaint was a nationwide practice of Defendants. Defendants conduct business
15 in the State of New Mexico. Upon information and belief, Defendants' actions
16 described herein occurred in the State of New Mexico as well.

17 926. This is a qui tam action brought by Relator and the State of New Mexico to
18 recover treble damages and civil penalties under the New Mexico Medicaid False
19 Claims Act, N. M. S. A. 1978, § 27-14-1 *et seq.* and the New Mexico Fraud
20 Against Taxpayers Act, N. M. S. A. 1978, § 44-9-1 *et seq.*

21 927. N. M. S. A. 1978, § 27-14-4 provides liability for any person who-

22 928. Presents, or causes to be presented, to the state a claim for payment under
23 the Medicaid program knowing that the person receiving a Medicaid benefit or
24 payment is not authorized or is not eligible for a benefit under the Medicaid
25 program;

26 929. Makes, uses or causes to be made or used a record or statement to obtain a
27 false or fraudulent claim under the Medicaid program paid for or approved by the
28

1 state knowing such record or statement is false;

2 930. Conspires to defraud the state by getting a claim allowed or paid under the
3 Medicaid program knowing that such claim is false or fraudulent.

4 931. N.M.S.A. 1978 § 44-9-3 provides liability for any person who-

5 932. knowingly presents, or causes to be presented, to an employee, officer or
6 agent of the state or to a contractor, grantee or other recipient of state funds a false
7 or fraudulent claim for payment or approval;

8 933. knowingly makes or uses, or causes to be made or used, a false, misleading
9 or fraudulent record or statement to obtain or support the approval of or the
10 payment on a false or fraudulent claim;

11 934. conspires to defraud the state by obtaining approval or payment on a false or
12 fraudulent claim;

13 935. conspires to make, use or cause to be made or used, a false, misleading or
14 fraudulent record or statement to conceal, avoid or decrease an obligation to pay or
15 transmit money or property to the state.

16 936. Defendants violated N. M. S. A. 1978, § 27-14-4 and N.M.S.A. 1978 § 44-9-
17 3 from at least 2005 to the present by engaging in the fraudulent and illegal
18 practices described herein.

19 937. Defendants furthermore violated N. M. S. A. 1978, § 27-14-4 and N.M.S.A.
20 1978 § 44-9-3 and knowingly caused thousands of false claims to be made, used
21 and presented to the State of New Mexico from at least 2005 to the present by its
22 violation of federal and state laws, including the Anti-Kickback Act, and Stark Act,
23 as described herein.

24 938. The State of New Mexico, by and through the State of New Mexico
25 Medicaid program and other state health care programs, and unaware of
26 Defendants' fraudulent and illegal practices, paid the claims submitted by health
27 care providers and third payers in connection therewith.

1 939. Compliance with applicable Medicare, Medicaid and the various other
2 federal and state laws cited herein was an implied, and upon information and
3 belief, also an express condition of payment of claims submitted to the State of
4 New Mexico in connection with Defendants' fraudulent and illegal practices.

5 940. Had the State of New Mexico known that Defendants were violating the
6 federal and state laws cited herein, it would not have paid the claims submitted by
7 health care providers and third party payers in connection with Defendants'
8 fraudulent and illegal practices.

9 941. As a result of Defendants' violations of N. M. S. A. 1978, § 27-14-4 and
10 N.M.S.A. 1978 § 44-9-3 the State of New Mexico has been damaged in an amount
11 far in excess of millions of dollars exclusive of interest.

12 942. Relator are private persons with direct and independent knowledge of the
13 allegations of this Complaint, who have brought this action pursuant to N. M. S. A.
14 1978, § 27-14-7 and N. M. S. A. 1978, § 44-9-5 on behalf of themselves and the
15 State of New Mexico.

16 943. This Court is requested to accept supplemental jurisdiction of this related
17 state claim as it is predicated upon the exact same facts as the federal claim, and
18 merely asserts separate damage to the State of New Mexico in the operation of its
19 Medicaid program.

20 944. Pursuant to the New Mexico Medicaid False Claims Act and the New
21 Mexico Fraud Against Taxpayers Act, the State of New Mexico and Relator are
22 entitled to the following damages as against Defendants:

23 945. To the STATE OF NEW MEXICO:

24 946. Three times the amount of actual damages which the State of New Mexico
25 has sustained as a result of Defendants' fraudulent and illegal practices;

26 947. A civil penalty of not less than \$5,000 and not more than \$10,000 for each
27 false claim which Defendants caused to be presented to the State of New Mexico;

1 948. Prejudgment interest; and

2 949. All costs incurred in bringing this action.

3 950. To RELATOR:

4 951. The maximum amount allowed pursuant to N. M. S. A. 1978, § 27-14-9 and
5 N. M. S. A. 1978, § 44-9-7 and /or any other applicable provision of law;

6 952. Reimbursement for reasonable expenses which Relator incurred in
7 connection with this action;

8 953. An award of reasonable attorneys' fees and costs; and

9 954. Such further relief as this court deems equitable and just.

10 **COUNT XXXI**

11 **(New York False Claims Act, N.Y. State Fin. Law § 187 *et seq.*)**

12 955. Relator re-allege and incorporate the allegations above as if fully set for
13 herein and further alleges as follows.

14 956. Additionally, Relator state that the course of conduct described in this
15 Complaint was a nationwide practice of Defendants. Defendants conduct business
16 in the New York. Upon information and belief, Defendants' actions described
17 herein occurred in New York as well.

18 957. This is a qui tam action brought by Relator and State of New York for treble
19 damages and penalties under New York False Claims Act, N.Y. State Finance Law
20 § 187 *et seq.*

21 958. N.Y. State Finance Law § 189 provides liability for any person who—

22 959. Knowingly presents, or causes to be presented, to any employee, officer or
23 agent of the state or a local government, a false or fraudulent claim for payment or
24 approval;

25 960. Knowingly makes, uses, or causes to be made or used, a false record or
26 statement to get a false or fraudulent claim paid or approved by the state or a local
27 government;